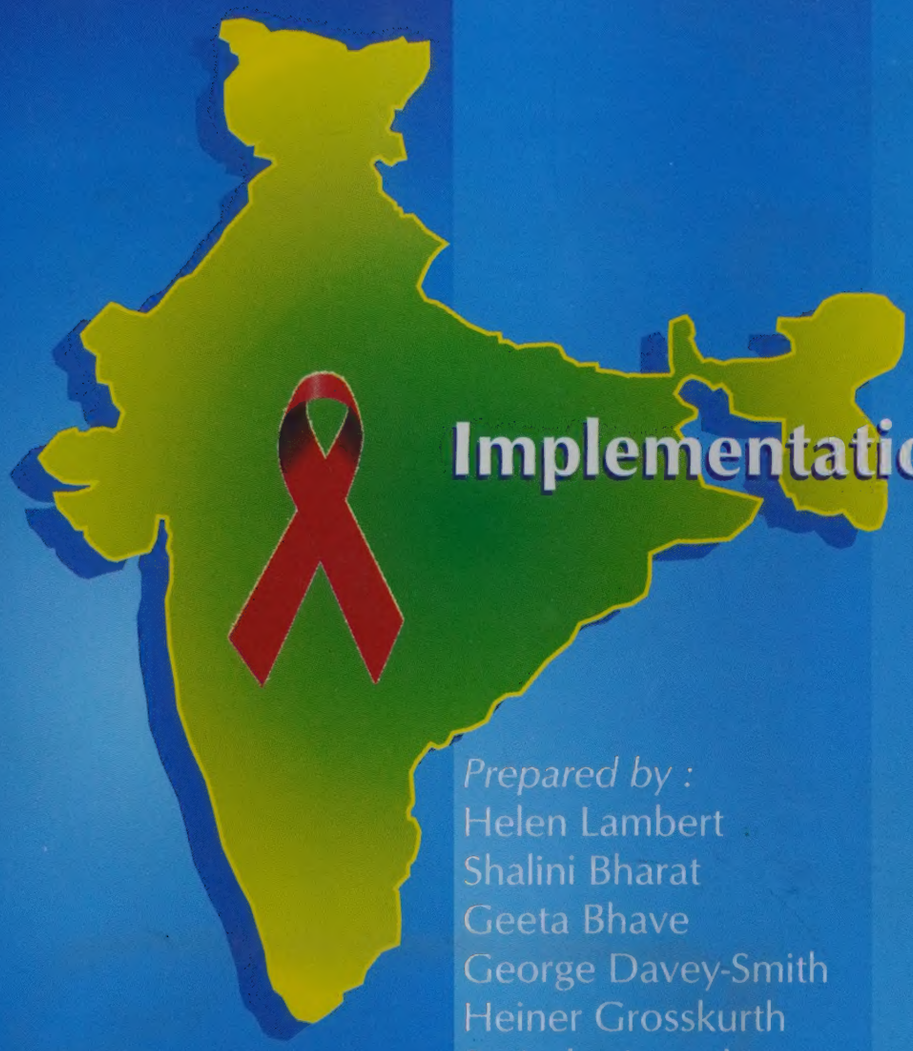
Situational Analysis of Sexual Health in India (SASHI)



Implementation Package

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On behalf of
National AIDS Control Organisation
Govt. of India

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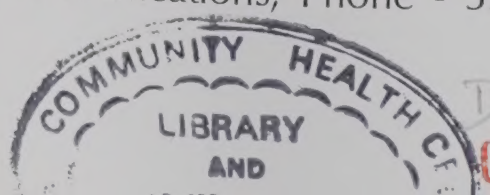

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FOREWORD

On behalf of the Government of India and as Project Director for the Government of India's National AIDS Control Organisation we have great pleasure in publishing the Situational Analysis of Sexual Health in India (SASHI) package. NACO believes that SASHI will add a significant contribution to our work and that of our colleagues and partners in our aim of posing an effective and timely response to the spread of HIV/AIDS in India.

India's response to the HIV/AIDS epidemic is stronger and more effective now than ever before and we believe that our work in the past is beginning to bear fruit in tackling the causes and consequences of the epidemic across India. That said, the epidemic continues apace and we recognise the need to be stronger, marshalling resources, information and skills as the epidemic continues to take hold in India.

A key part of an effective response to HIV/AIDS is in building an informed basis for policy making and planning at national, state and at local level. NACO and its development partners have done much to advance this aim in India but we recognise that we must continue to collectively develop our skills and resources in this area. We believe that SASHI will add real value to all levels of our response, bringing together specific behavioural and epidemiological information in a manner which is accessible to planners and sensitive to local contexts and needs. We are facing similar challenges to ourselves and we welcome widespread use of the methodology.

Following publication to the package and with the support of our partners, NACO will support State AIDS Control and Prevention Societies to integrate the package within their response and demonstrate the contribution that SASHI can make in preventing HIV transmission, enabling us all to further meet our goals.

NACO is grateful to the Government of the United Kingdom's Department for International Development in India for support to SASHI and to the many colleagues and individuals who have worked to develop this package.

J V R Prasada Rao,
Additional Secretary and Project Director,
National AIDS Control Organisation,
Ministry of Health & Family Welfare,
Government of India

April 23, 2001

PREFACE

The need for action to improve sexual and reproductive health and to prevent the spread of HIV in India is now well established. Yet in India as in many other contexts, policy makers and planners lack access to high quality context-specific information about sexual health and sexual behaviour. This information is essential for deciding what forms of HIV prevention activities are needed in any particular place and what forms combinations of interventions would be most appropriate in forming an effective response. This package provides a strategy for collecting this kind of information, known as Situational Analysis of Sexual Health in India (SASHI). When implemented SASHI will provide an accurate and broad-ranging picture of the situation on which decisions about disease prevention and health promotion strategies can be based.

This comprehensive implementation package for conducting situational analysis goes beyond existing approaches in several ways; the study protocol covers the private as well as the public health services and those who use them; and it includes qualitative as well as quantitative data collection techniques in order to gain access to sensitive information and ensure greater validity of the findings.

Separate chapters describe in detail how to monitor, record, analyse and write up the data obtained as well as how to collect these data; and data collection guides and recording forms for every step of the data collection process are provided. Options for adapting the protocol to suit local circumstances and needs are also provided.

Background of SASHI

The Government of the United Kingdom's Department for International Development in India (DFIDI) has been supporting the Government of India through the National AIDS Control Organisation, NACO and State Government to prevent the transmission of HIV since the mid in 1990s. During the early phase of DFIDI's support, discussions with NACO indicated that planners on local conditions, prevalence of sexually transmitted infections, or nature and extent of high risk sexual behaviour. This information is vital in enabling planners to appropriately respond to the epidemic, deciding what kinds of interventions should have the highest priority in any given location.

Therefore a multidisciplinary and multinational (Indian and European) team co-ordinated from the London School of Hygiene and Tropical Medicine, UK was commissioned by DFIDI to develop a strategy for undertaking situational analysis involving the rapid collection of this kind of information. The SASHI team designed a protocol for data collection and then trained local researchers in two selected pilot sites (Jamnagar, Gujarat and Trivandrum, Kerala) to implement the protocol, assisting

them in technical aspects of the data collection and analysis. After reports of the findings for each site had been completed for local use in planning, the protocol was thoroughly reviewed and modified using the experiences gained. The revised protocol is provided in this package (as Chapter 5 and Appendix 5.1), along with additional chapters that have been complied to provide guidance for potential users of SASHI concerning the administrative, training, ethical, data and resource management, personnel and other dimensions of SASHI.

The SASHI approach is interdisciplinary and includes collection of both qualitative and quantitative data on social, cultural, behavioural, clinical, epidemiological aspects of sexual health in the selected research area. The data collection and analysis stages are intended for use by local terms of researchers, with technical support from experts in these activities.

All the tools needed for collection of data are provided in this packages, personnel and facilities are needed to carry out a useful situational analysis of sexual health.

SUMMARY OF THIS PACKAGE

Chapter 1 of this package describes *when* SASHI was developed, giving a brief background about sexual health and the HIV epidemic in India and setting out the need for certain kinds of information. Chapter 2 describes *what* SASHI is, *who* should use this package and *where* and *when* it can be use, *what* information will be provided as a result of using it and *how* the package can be adapted to local circumstances. In Chapter 3, the planning and decision-making activities that must be carried out before the SASHI approach can be used are summarised. Chapter 4 provides details of the training needed for local researchers to able to carry out SASHI data collection. Chapter 5 is the protocol for data collection, which describers in detail all the data collection procedures required to carry out a Situational Analysis of Sexual Health in India. Important ethical issues are involved in studying sexual health and these are discussed in Chapter 6. Chapter 7 describes how to record all the data will be collected during a situational analysis of sexual health and suggests procedures for monitoring this key activity. Guidelines on how to analyse the data that are collected are provided in Chapter 8, in which details of the steps required to write up the results in the form of a readable report are also set out. Chapter 9 discusses the management and supervision needs for carrying out a situational analysis and sets out the roles of key personnel. Finally, Chapter 10 describes the kinds of information that are obtained by carrying out SASHI and how these can be used in various ways.

The appendices to each chapter contain more technical information that will be needed by users of this package. Appendix 2.1, for instances, specifies the different types of laboratory test that can be carried out using the three versions of the SASHI Protocol; Appendix 3.2 covers office requirements; and Appendix 5.1 contains all the data collection guides needed to implement the SASHI protocol and all the recording forms that will be needed for documenting the data that are collected.

A reader who wants to get an initial idea of what SASHI covers and what it is for, could turn first two Chapters 2 and 10, followed by chapter 5. Table 1 in Chapter 2 gives a useful summary of what kinds of data collection SASHI includes and why they are useful to planners of sexual health promotion and disease prevention projects. Readers who are actively considering the use of this package in their own area or project can also consult Table 2 in the same chapter, which shows how SASHI can be modified to suit different settings with varying amounts of resources and expertise. They should then look at chapters 3 and 4 to see what will be required in practical terms before they can embark on conducting SASHI. Chapter 5, 7, 8 and 9 are 'how to' chapters that will need to be studied in detail by anyone involved in actually carrying out SASHI. Readers wanting to know precisely what data are collected and what procedures actually take place during SASHI are advised to browse through Chapter 5 and its appendices after consulting Table 1 in Chapter 2.

TABLE OF CONTENTS

Contents marked * not yet complete.

ABBREVIATIONS USED IN THIS DOCUMENT

AIDS	-	acquired immunodeficiency syndrome
BSc.	-	Bachelor of Science
BV	-	bacterial vaginosis
CA	-	Candida albicans
CO	-	carbon dioxide
CRT[2]	-	Central Resource Team
CT	-	chlamydia trachomatis
DfID	-	Department for International Development
DMLT	-	Diploma in Medical Laboratory Technology
EIA	-	enzyme immunoassay
ELISA	-	
HD	-	Haemophilus ducreyi
HIV	-	human immunodeficiency virus
HSV-2	-	herpes simplex virus type 2
HRB	-	high risk (sexual) behaviour
LGV	-	lymphogranuloma venereum
MBBS	-	Bachelor of Medicine, Bachelor of Surgery
MD	-	Doctor of Medicine
MSc.	-	Master of Science (postgraduate degree)
MSM	-	men who have sex with men
NACO	-	National AIDS Control Organisation
NG	-	Neisseria gonorrhoeae
NGO	-	non-governmental organisation
NSU	-	non-specific urethritis
PCR	-	polymerase chain reaction test
PhD	-	Doctor of Philosophy (postgraduate research qualification)
RG	-	Resource Group
RMP	-	Registered Medical Practitioner
RRP	-	Regional Resource Person(s)
RTI	-	reproductive tract infection
SAC	-	State AIDS Cell
SAS	-	State AIDS Society
SASHI	-	Situational Analysis of Sexual Health in India
SSO	-	Senior Scientific Officer
STD	-	sexually transmitted disease
STI	-	sexually transmitted infection
SW	-	sex worker
TP	-	Treponema Pallidum
TPHA	-	Treponema Pallidium haemoagglutination assay (syphilis test)
TV	-	Trichomonas vaginalis
UK	-	United Kingdom
VDRL	-	Venereal Disease Reference Laboratory (syphilis test)

CHAPTER 1

Why is SASHI Needed?

Introduction

This chapter highlights the role of SASHI (SITUATIONAL ANALYSIS OF SEXUAL HEALTH IN INDIA) in public health terms by summarising the present scenario relating to sexual health, particularly the HIV epidemic in India. It describes the links which exist between HIV infection and other types of sexually transmitted diseases, explaining why SASHI includes a collection of data on these other kinds of infections. It discusses social dimensions of HIV, demonstrating why a multidisciplinary approach, as used in SASHI, is essential for gathering the kinds of information on sexual health and sexual behaviour needed to make decisions about what types of interventions will improve sexual health and prevent HIV transmission at local level.

HIV infection - A major public health problem in India

AIDS and HIV infection are a growing health problem in India. The World Health Organisation has projected that, by the year 2000, there will be more people with HIV infection in India than in any other country. The number of HIV infected people in India is impossible to identify accurately, although current estimates place this at around 1.5 million (1999). The number has certainly increased rapidly over the last decade and it is anticipated that HIV infection will be an increasingly important cause of ill-health and death in India over the coming years.[1]

The level of HIV infection varies widely between areas and populations within India. High prevalence rates have been found in sexually transmitted disease (STD) clinic attenders in the Maharashtrian cities of Mumbai (Bombay) and Pune (25-40%)[2], intravenous drug users in Manipur (>50%), STD clinic attenders in Manipur and Goa (10-20%) and commercial sex workers in Mumbai (up to 70%). Prevalence rates among general population groups still tend to be comparatively low, mostly below 1.0%. However, there are notable exceptions, with surveillance systems reporting rates of around 3% among antenatal clinic attenders in Mumbai and 4% in Pondicherry. Similar rates are seen among blood donors and there are higher rates in routine hospital admissions. In Tamil Nadu a prevalence rate of 7% has been reported from health camp attenders in both urban and rural areas.[3] While these preliminary studies require confirmation before one can be certain that such high rates exist in general population groups, these demonstrate the potential for a major HIV epidemic in India.

Clearly, the geographical distribution of HIV is very uneven. However, currently available data remain inadequate for a precise characterisation of where and how the epidemic

will spread. Little is known about the socio-economic determinants of HIV transmission in India. Yet, only if these are better understood will it be possible to design well targeted and cost-effective interventions.

Social dimensions of HIV infection

The biological and behavioural determinants of STDs and of sexually transmitted HIV infection are similar and the next section will suggest that common preventive and control strategies often need to be applied. For both HIV and STD infection, however, many of the broader socio-cultural and economic conditions under which transmission occurs are not sufficiently known or understood to be able to design effective interventions. In every country where HIV exists, the patterns of spread indicate that vulnerability to HIV is associated with certain structural features. These include the socio-economic characteristics of poverty, social marginalisation and discrimination. It is essential that attempts to control and prevent HIV and other sexually transmitted diseases do not ignore these social dimensions, but actively consider them while designing appropriate strategies. Otherwise, targeted interventions are not only less likely to be successful, but may run the risk of increasing the stigma and social exclusion of vulnerable communities and individuals.

SASHI emphasises collection of fairly specific data relating to treatment-seeking behaviour, STDs and other aspects of sexual health but this is not intended to obscure these important social dimensions in any way. There are two reasons why the medical, health and behavioural aspects are relatively prominent in the SASHI protocol in comparison with a focus on structural determinants of sexual health. The first is that awareness of the possible control of STD as a means for controlling the HIV epidemic is still quite limited among many planners, programme managers and non-governmental organizations. There is a common assumption that the only possible interventions for HIV prevention are initiatives focused on behavioural change (whether, for example, through health education to increase awareness of what constitutes risk behaviour, or health promotion to encourage condom use among those practising high risk behaviour). Collection of information concerning other aspects of sexual health, including prevalence, treatment and treatment-seeking for STDs, can help to highlight alternative strategies for improving sexual health.

The second reason for this focus in data collection is that general data and observations about the structural vulnerability of, for example, poor people and especially women, are likely to be of limited practical value for developing readily implementable interventions within any local setting (whereas they should, for instance, have central importance in regional or national social policy formulation). Moreover, observations about broad structural characteristics and tendencies are likely to be universally true and can often be made without collecting primary data. Therefore, the SASHI protocol focuses more on collecting those data that are likely to be helpful in the development of locally feasible interventions. This does of course still include the collection of detailed data

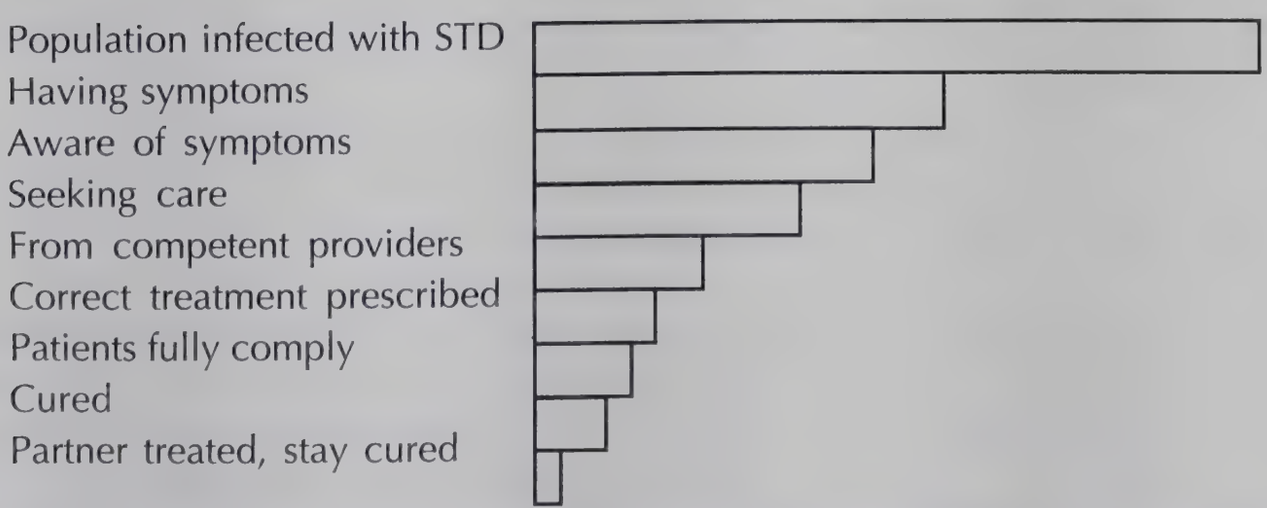
on social aspects of sexual health. Proper analysis of these data will allow assessment, for example, of varying vulnerabilities across different sections of the local population, that in turn can be used to identify local social determinants of risk for HIV and other sexually transmitted diseases. Such identification will help indicate what kinds of, and foci for, intervention are likely to be most effective and appropriate in the local setting.

It is also important to note that social dimensions of sexual health require careful attention in any intervention that is developed, regardless of whether it is primarily 'medical' (for example, provision of improved STD clinical services) or 'social' (for example, improvement of occupational and social conditions for sex workers) in its primary focus. Overall principles apply to the development of any public health intervention - and particularly those that relate to sensitive and personal areas of people's lives - including the need to address perceived needs of the population at which the intervention is aimed, to involve people who are the intended beneficiaries in a participatory manner, and to avoid doing harm in any way. These principles should apply to any intervention that may ultimately be implemented as a result of initiating SASHI and it is vital that they be taken into active consideration once a situational analysis is implemented, when its findings are interpreted and most of all, when decisions are being made regarding implications of the findings for intervention.

STDs and their relationship with HIV infection

Sexually transmitted diseases (STDs) are a major public health problem in India and elsewhere. According to the World Development Report of 1993, STDs and other reproductive tract infections (RTIs) are the second most important reason world-wide for the loss of healthy life years in women of childbearing age. Particularly in women, STDs frequently lead to various complications and consequences, such as pelvic inflammatory disease, puerperal sepsis, tubal blockage, ectopic pregnancy, infertility or chronic pain. STDs often lead to abortion, stillbirth, premature delivery, and sequelae may include low birth weight, congenital syphilis and blindness as a consequence of ophthalmia of the newborn.

Figure 1: Piot's model for STDs



For some years it has been known that STDs enhance HIV transmission. Association

between both types of infection has been observed in many cross-sectional and longitudinal studies. Infection with a STD is likely to increase susceptibility to infection with HIV. Conversely, in HIV-infected men and women, the shedding of HIV in genital fluids is greatly increased in the presence of gonococcal, chlamydial and trichomonal infections and in the presence of genital ulcers, and this increase is independent of the viral load in the blood. Treatment of these conditions can drastically reduce genital HIV shedding. STD interventions have been shown to greatly reduce the rate of new HIV infections (HIV incidence) in sex workers in several intervention studies from Africa and Asia. A randomised controlled trial of improved treatment services for STD patients in an area with high STD and still low but rising HIV prevalence has shown that the incidence of HIV infection in the general population can be substantially reduced through this intervention.

Information regarding prevalence and incidence of STDs in India is limited. Most data come from government dermatovenereology clinics, but it is clear that only a small minority of people with STDs attend these clinics and such data are therefore of limited value. With the increasing interest in women's reproductive health over the past decade, several studies of reproductive tract infections (RTIs) in women have been carried out, which generally demonstrated high rates of infection. It is likely that there is a considerable burden of STD in India, but a serious deficiency in the knowledge base regarding the incidence and prevalence of major STDs in the general population remains.

Importance of a multidisciplinary approach

Some of the factors which determine the level and the role of STDs in a population can be described by means of the model laid out in figure 1 (known as the 'Piot model'). In any given community, a certain proportion of the population may be infected with an STD. However, many people with an STD are asymptomatic and, therefore, will not seek treatment. Also a number of those with symptoms may not seek treatment for different and often unknown reasons. For those seeking treatment, incompetent providers will often be the only source of care. But even if STD patients reach a well trained medical practitioner or specialist, their sexual partners usually remain untreated, and thus reinfection is likely to occur. Only a small fraction of infected persons will eventually be and remain cured.

Population infected with STD Having symptoms Aware of symptoms, Seeking care from competent providers, Correct treatment prescribed, Patients fully comply, Cured partner treated, stay cured *Figure 1: Piot's model for STDs*

It has been shown in studies elsewhere that at each steps of the model a substantial proportion of people with an STD 'drop out'. No data are available from India which would allow estimates to be put on the size of the proportional losses. Yet realistic estimates are required if evidence based design of interventions according to the needs identified is to occur. Data may vary between different countries, and between different groups of the population within countries. This is of particular importance in a country

like India with its great socio-cultural diversity, and the many different occupational and economic conditions likely to influence risk behaviour and treatment seeking behaviour.

The model can be used to consider systematically the options available for improved STD control. These are:

- primary prevention of STDs in those who are not infected
- screening of individuals with asymptomatic infections
- screening of patients with symptomatic but neglected STDs
- improvement of treatment seeking behaviour
- improvement of STD treatment services
- improvement of partner notification and treatment

Good STD treatment services will solve a part of the overall problem. Effective interventions need to address other steps of the model and, therefore, answers are needed to questions such as: What are the factors determining sexual behaviour in the first place? Which social, economic and cultural factors put people at risk? Are they in a position to reduce that risk? What proportion of people with STDs or RTIs have asymptomatic infections? Why do some patients not seek treatment? And of those who do: Why and where are they going? How effective is the treatment given by different service providers? Does the quality of services require improvement? How best could this be achieved? Can the sexual partners of patients be reached and treated?

Answers to these types of questions require a multidisciplinary approach capable of gathering not only medical but social, cultural and behavioural information. For example, a question such as 'How can we improve effective treatment for STDs?' is based upon the medical knowledge that this reduces overall morbidity and also the risk of HIV transmission. To answer this question however, we first need to ask where people currently seek treatment and, if they do not seek treatment from good quality biomedical services, why do they not do so. Finding out that people do not seek treatment from such services because they are not available would indicate the need for a very different kind of intervention from that required after finding out that people do not seek treatment because they are not aware of them or because they do not know which symptoms they need to seek treatment for. We also need to ask which STDs are prevalent in order to determine what sort of treatment is likely to be effective.

Similarly, the question, 'How can we reach the sexual partners of STD patients?' is based upon the medical knowledge that treating the partners of these patients is beneficial in controlling these diseases. We cannot answer the question though, nor decide whether this strategy is likely to work in a particular situation, without first learning who and where the sexual partners of these patients are likely to be and to what extent it is possible to contact them. Only then can the feasibility of developing an intervention to STET them be assessed and decisions made about what such an intervention would

involve. Some answers may be found within medical settings, for example, by careful interviewing of STD patients themselves, but very often gathering the kind of information that is needed means going beyond the clinic into the wider population. Therefore, SASHI has social scientists working closely with clinicians to gather information from, and about, not only patients but a whole variety of people in different communities and occupations, from local experts such as private medical specialists and pharmacists, to people who are likely to be most vulnerable to HIV infection and other sexual and reproductive health problems. To provide answers to all these underlying questions a multidisciplinary, multimethod approach to collecting data is needed, in which medical and social researchers work closely together. SASHI uses a methodology which is designed to provide such an approach.

Why is multidisciplinary situational analysis needed?

Currently, in most places, although there is awareness of the need to develop intervention strategies for HIV prevention, there are also large gaps in the kinds of knowledge described above, together with common but often inaccurate assumptions. Implementing interventions on the basis of assumptions about what should be done when there is inadequate information about the realities of the local situation can lead to inappropriate interventions or a lack of interventions that are needed. Either situation constitutes a waste of resources (as when time and money are put into interventions that are not properly designed or focused and so do not work) and can cause harm. For example in one of the sites where SASHI was piloted, a general decline in the number of patients with gonoccocal urethritis presenting at the Government dermato-venereology clinics had been seen. Locally it was assumed that this meant fewer infections of this type were occurring.

However, there were other possible explanations: perhaps fewer patients were being seen at these facilities overall, because they increasingly prefer treatment in the private sector; perhaps individuals who have already had this infection are increasingly familiar with drugs that they can use for self-medication, so they do not perceive a need to consult a doctor; or again, perhaps due to an increase in antibiotic-taking among the population generally, this particular type of infection is not producing symptomatic effects which lead patients to seek treatment. Without gathering information on the actual situation, it is impossible to know which of these possible explanations is correct. In fact, by collecting data carefully from private as well as public clinics, the SASHI study showed that gonorrhoea was more common among patients than local authorities had thought and also that male patients were frequently self-medicating or visiting treatment providers who did not prescribe adequate treatment. To have *assumed*, from looking only at the pre-existing clinic-based data, that the initial explanation was correct and, therefore, there was no need to focus on the control of gonoccocal urethritis because it is so rare, would have been potentially detrimental to population health, since having this infection greatly enhances the risks of transmitting or becoming infected with HIV and causes many other reproductive health problems, especially among women.

It is also common to choose particular types of intervention without having sufficient evidence to indicate that they will do any good, especially in the areas of training and education. For example, during one of the SASHI pilot studies it was found that an intervention to educate women in slum communities about STDs and HIV had unintentionally resulted in some women becoming more rather than less reluctant to seek help for any suspected reproductive tract infection. Thus not only substantial resources are wasted by adopting inappropriate and therefore ineffective approaches, but valuable time is wasted while the HIV virus spreads unchecked. SASHI is designed to provide the knowledge that is needed to make initial judgements about which interventions are likely to be most useful, most urgently needed and most appropriate for a particular setting. The next chapter describes just what SASHI does (and does not do) and how it should be used.

Why is the SASHI approach valuable?

Besides providing multidisciplinary methodology needed for ensuring that adequate information is collected, SASHI is particularly valuable for use in India since it will provide consistency and comparability. As SASHI is conducted in different sites and because the same methodological approach is being used each time, the data can be directly compared. In turn, the knowledge gained will be cumulative, allowing generalisations to be made across India since different sites and regions are covered. Thus the overall knowledge base will be improved. Hence, not only will the starting point for each 'situational analysis' in the future be better established, but general conclusions and trends derived from the accumulated SASHI findings in different sites can be applied to locations where SASHI either has not yet been or cannot be conducted. Finally, the use of a common and consistent methodology repeated over time allows for time trends to be examined.

Notes

1. Bollinger R C, Tripathy S P & Quinn T C. (1995). The human immunodeficiency virus epidemic in India: Current magnitude and future projections. *Medicine,* 71 (2): 97-106.

2. Rodrigues JJ, Mehendale SM, Shepherd ME, et al. (1995) Risk factors for HIV infection in people attending clinics for sexually transmitted diseases in India. *BMJ*, 311:283-286.

3. Solomon, Suniti et al. (1998). Prevalence and risk factors of HIV-1 and HIV-2 infection in urban and rural areas in Tamil Nadu, India. *International Journal of STD and AIDS*, 9:98-103.

CHAPTER 2

What is SASHI and What does it do?

Introduction

This chapter explains the purpose of SASHI, what it does and who it is for. It discusses the settings in which SASHI can be used and who should carry it out, before going on to summarise the various data collection steps involved and explain in detail the rationale for the kinds of data that are gathered and the methodological approaches that are used. Finally, it sets out the various options for implementing SASHI at different levels of complexity and describes how the protocol can be modified to take into account variations in circumstances, needs and resources in different settings. All characteristics of SASHI that are described here are based on having field tested (or 'piloted') the methodology used in two different Indian sites and having subsequently revised the approaches and tools that are recommended on the basis of this experience.

What is SASHI and who is it for?

SASHI is a strategy for analysing the situation relating to sexual health and high risk sexual behaviour in a known geographical area. It uses a set of methods and techniques, set out in the protocol, provided in *Chapter 5* of this package, to collect information. The kinds of data which result from carrying out SASHI will help planners to decide whether interventions to improve sexual health and prevent HIV are needed in their area and if so, what kinds of interventions should be prioritised and where they should be focused. Any organization, institution or agency with responsibility for developing interventions to prevent HIV infection and promote sexual health in an area could find SASHI useful in decision-making. It is particularly designed for planners and policy-makers who need to assess priorities and allocate resources in a designated geographical area, but who may lack the necessary information on which to base this prioritisation and allocation. Possible users, therefore, include Governmental agencies and in particular, State AIDS Control Societies, Directorates of Health Services and Ministries of Health and Family Welfare; large non-governmental organizations (NGOS) that are working in fields relating to reproductive and sexual health that need information to plan in relation to HIV prevention; and large NGOs that are working for the welfare of certain populations or in particular settings where they feel vulnerability to HIV infection may be an issue requiring attention, but have inadequate information on which to base assessment or intervention development.

Where can SASHI be used?

The SASHI protocol for collecting data (*Chapter 5 and Appendix 5.1*) is designed for use in a pre-selected geographical location, such as a city, a town, or a group of rural

settlements, peri-urban suburbs or slum neighbourhoods. It was first piloted in two medium sized urban areas (populations of roughly 500,000 and 800,000) and is flexible enough to be used in smaller and larger areas. Parts of the protocol indicate where sampling frames or selections of informants will differ according to the type of site. If a situational analysis of a major city or a large geographical area such as a District or wider region is needed, SASHI will either need to be carried out several times in different locations in order to cover the entire geographical area, or the protocol itself will need to be adapted by experts who are familiar with rapid assessment and research sampling (such as members of the SASHI 'Resource Group' - see section on 'who should carry out SASHI'). Although most of the information generated by conducting SASHI will refer to the main site in which the situational analysis is carried out, useful and relevant information about surrounding places and populations will also emerge, particularly about locations of economic importance and sites of migration that are connected with the main site. In some instances, conducting SASHI might show that the greatest need for developing an intervention is not within the selected site itself, but in an adjacent or connected place.

What does SASHI provide?

Carrying out SASHI will not necessarily result in a detailed plan of the intervention project(s) that is/are needed in a particular site, but it will provide the information that is needed to make an overall assessment of the situation and to make initial decisions about where to focus resources and where to carry out further studies or needs assessments. It is, therefore, particularly valuable for use in places where little is known and only very selective data are available. Carrying out SASHI could also help in initiating interventions by establishing contact with hard-to-reach populations. Information gathered through SASHI can also be used as baseline information that will later be required for the monitoring of sexual health and its determinants, and for the evaluation of intervention projects.

SASHI is primarily designed for use in medium sized locations (such as cities or groups of rural settlements) and for gathering data on *all* possible vulnerable populations and situations in that site. On this kind of scale it would probably need to be followed up by detailed needs assessments of any particular populations or settings which are identified through SASHI as being likely to require interventions. Such needs assessments should build on the initial contacts that have been made during the course of SASHI and involve local participants fully.

When conducted in a medium or large site, a participatory approach (involving data collection or related activities by community members) will not usually be suitable within SASHI itself. This is because a key objective of SASHI is to identify potentially vulnerable populations and it may be impossible to involve representatives of some of these populations to participate in SASHI data collection before the situational analysis has actually been conducted, since these populations may not yet even have been identified.[1]

Also, even where there is some knowledge of and contact with such populations in a site, before SASHI has been carried out it may not be known which out of the many possible sub-populations and locations should take the highest priority for development and implementation of interventions. Also, in larger sites it is not practical to try to involve representatives from all communities while working on SASHI; inviting representatives only of certain groups to undertake the situational analysis may bias the findings towards developing interventions only for those groups. On the other hand, where community groups or representatives, or organizations working with particular communities or sub-populations, are already in place they should always be involved as much as possible in SASHI in ways that are appropriate (whether by facilitating access to certain settings and informants, or gathering data for particular study components).[2]

The need to carry out separate and subsequent needs assessments, and the restrictions on participatory or action research, apply to the sorts of medium-to-large sized sites in which SASHI was originally piloted and in which the methodology is most likely to be applied initially. However, SASHI can also be carried out in smaller, more self-contained and easily documented sites. In such cases - for example, a large village or small town, an industrial area, a tourist site or a single urban slum - carrying out SASHI should itself provide sufficiently detailed information for the study to act simultaneously as a needs assessment. In these sites, it may not be necessary to conduct subsequent focused needs assessments in particular populations or settings, since sufficiently detailed assessments can be made during SASHI itself. It is also more feasible in smaller sites to carry out SASHI with more intensive input from community members. In such settings therefore, SASHI can feed directly into the design and development of appropriate interventions, with review of SASHI findings leading into decision-making about, and immediate initiation of, the interventions indicated by SASHI findings as being most urgent, necessary, useful and appropriate for the site.

Who should carry out SASHI?

SASHI is designed in such a way that it can be implemented by local researchers, together with the support of a *'Resource Group'* of technical experts. These experts must be familiar with the principles regarding the use of rapid assessments and have the specific disciplinary and methodological skills that are necessary for implementing SASHI successfully. Details of personnel and other local requirements are given in *Chapter 3* (*Planning for SASHI*) and in *Appendix 3.1* (*Personnel Requirements*). Assistance from the resource group or equivalent local technical experts will be essential, particularly at the beginning of the SASHI process, to train local research team and at the end, to analyse, interpret and write up the findings. Ongoing inputs from resource persons during actual implementation of SASHI will also be most useful. Over time, if SASHI is undertaken on different occasions for various sites in a region, a local resource group of technical experts who have gained experience from previous involvement in the implementation of SASHI in that region could be developed.

What does SASHI include?

Table 1 summarises the steps and stages of data collection that make up SASHI, giving a rationale, or explanation, as to why each component is included in a situational analysis and why the information that will result from carrying out that component of the study is needed. In the left-hand column of the table the overall 'stage' (indicated alphabetically) of data collection is listed and its purpose summarised; in the right-hand column, each 'step' (indicated numerically) included in that stage is listed and its purpose is summarised. The section following this table discusses how SASHI can be implemented and which steps could be omitted in particular circumstances. These stages and steps correspond to the ones listed in the research protocol (provided in *Chapter 5* and available on disk), which describes in more detail exactly who carries out each step (some are carried out by social researchers, some by medical researchers, and some by both), which data are to be collected and what method is to be used. The protocol also describes the purpose of each stage and what data collection activities are involved.

TABLE 1: SUMMARY AND RATIONALE OF SASHI PROTOCOL

STAGE	STEP
A: COMPILATION OF EXISTING DATA The first stage concentrates on compiling whatever data already exist. To find out what is already known saves time and resources by avoiding unnecessary duplication of effort. Also existing information will be used to help plan subsequent stages of SASHI and to identify experts who can provide further useful information and assistance if needed.	***A1: Existing sources of socio-economic and behavioural data.*** Compiling existing information on socio-demographic characteristics of the population, sexual and reproductive health, treatment-seeking behaviour and any specific studies on potentially vulnerable populations will provide some basis for comparison and evaluation of the social data to be collected later. It will also help to focus the subsequent social research activities on certain populations and areas.
	A2: Existing sources of epidemiological data. Building up a picture of STD, RTI and HIV prevalence in local populations from existing information will provide some comparative material to add to and help evaluate the medical data that will be collected during SASHI itself.
B: SITE MAPPING. It is essential to obtain a general overview of the site first, in order to decide the focus (in terms of both people and places) of subsequent data collection activities. It is also necessary to gain cooperation and assistance from key local people.	***B1: Obtaining information and approval from officials.*** It is important to get approval from senior officials to carry out data collection activities in their area and to obtain cooperation and help from their more junior officials, who are likely to have more relevant concrete knowledge. Recommendations about knowledgeable individuals can also be obtained.
	B2: Interviews with key informants. In-depth informal interviews with individuals - both junior officials and private citizens - who have direct knowledge about people practising risky sexual behaviour and places where this occurs, can provide vital information as well as access to these people and places.

B3: Mapping sites and locations. Observational mapping provides a way of checking and supplementing verbally reported information about high risk activities and their locations. In some cases it can also provide an estimate of the numbers of individuals engaged in these activities and it will also identify locations where subsequent interventions may be focused.

B4: Mapping facilities for STD treatment. This step will provide necessary information for identifying places where some of the later steps in the SASHI study should take place. It will also indicate what types of facilities should be included in any subsequent interventions aimed at improving STD treatment and providing health education and information.

C: DATA COLLECTION ON HEALTH AND SEXUAL BEHAVIOUR. The information collected in this stage is important for identifying what kinds of risky sexual behaviour are occurring, where they take place and who is likely to be most vulnerable to STD/HIV infection. It will also cover what local populations think about signs and symptoms of STDs, what they do if they think they have a reproductive tract infection and to what extent they consider themselves to be at risk. Health promoting interventions that are appropriate and effective need to be based on such knowledge of what people really think and do.

C1: Doing participant observation in hard-to-access populations and places. This step will help to get access to very sensitive information such as where and how men wanting sex with other men meet one another and what risky sexual behaviour occurs; or which hotels arrange or allow commercial sex workers on the premises. Data collected through informal participant observation may be essential but difficult to gather by any other means.

C2: Conducting group discussions with women. These discussions are for learning what women in local communities know about high risk sexual behaviour, STDs, RTIs and HIV and whether they perceive themselves to be at risk. These are also used to identify potential case histories for step C3 and individual interviewees from vulnerable populations for step C4.

C3: Conducting group discussions with men at high risk (occupational groups). By this point in the study men working in certain occupations will have been identified as likely to be particularly vulnerable to infection. This may be because of their occupational circumstances (e.g their mobility, as in the case of transport workers; or their situation of living away from their families, as in the case of migrant industrial workers; or their access to vulnerable females, as in the case of policemen or labour contractors on building sites). A good way to gather information from such men is to hold informal group interviews, often at or near their workplaces.

C4: Collecting illness case histories (community based). This step helps to acquire detailed knowledge of what individuals in the community do when they have an RTI or STD, as well as what they think about the possible causes and transmission of such conditions. Some patients who come to government or private specialist clinics will be interviewed in other steps, but not all those who have infections attend these clinics. So clinic patients are not representative of all those who get RTIs/ STDs. These case histories can, therefore, provide a more balanced picture of other treatment-seeking strategies, including self-treatment. Case histories will also provide more in-depth information about perceptions of symptoms relating to STDs and RTIs, sources of information about these infections, influences on decision-making about treatment and, where informants are open and rapport is good, about individual sexual histories.

C5: Interviewing individuals practising high risk behaviour and members of vulnerable populations. These people should be the

principal beneficiaries of any subsequent interventions aimed at improving sexual health, so it is essential to obtain accurate information from them directly. Members of vulnerable populations in SASHI can also help to lay the groundwork for their active involvement in any later interventions.

D: STUDY OF STD/RTI SERVICES. This will help to identify areas where service provision can be improved and locations where sexual health promotion advice can be given in subsequent interventions. Therefore it is not confined to qualified specialists but includes study of a much wider range of service or health providers (from medicine shops to homeopaths and traditional practitioners).

D1: Making surrogate client visits to practitioners. This is the only really accurate way of learning what type and quality of care and advice is actually provided by medical practitioners to people with sexual and reproductive health problems. This information is needed to be able to determine whether interventions are advisable for improving clinical management of STDs/RTIs, provision of information and advice-giving about disease prevention, including promotion of condoms, in clinical settings.

D2: Conducting interviews and observations at pharmacies/medicine shops. Pharmacies or medicine shops are important types of health providers in India, where advice and information as well as medicine may be provided. Self-treatment with medicines bought at pharmacy shops is common in some places. The methods used in this step help to produce estimates of the extent of self-medication for sexual and reproductive health problems, information on condom sales and characteristics of persons purchasing condoms and seeking treatment for STDs/RTIs. These data can be used to assess how serious the potential for development of antibiotic resistance (through inappropriate self-treatment) is and also whether there is potential for providing sexual health promotion and disease prevention advice and information through pharmacies.

D3: Conducting interviews with practitioners. Valuable information about what kinds of people seek treatment from which sources, what types of treatment practitioners think they should provide and what the constraints on their practice are can be obtained from interviewing them. These data will add to those obtained from patients themselves and can be used to guide interventions focused on improving provision and quality of care or appropriate treatment-seeking behaviour.

D4: Facilitating collection of patient data by practitioners. These data will provide an estimate of the percentages of new STD/RTI cases consulting with a selection of public and private health care providers. In turn this will allow some evaluation of the relative importance of different sectors and types of practitioners in providing treatment for STDs/RTIs. This is necessary in order to decide where any intervention associated with the treatment of existing infections should be focused.

D5: Doing exit interviews with STD patients. These interviews will allow information to be gathered on quality of care and patient satisfaction in different types of treatment setting. Such information can be used to evaluate the need for interventions to improve patient care and management of STDs/RTIs. It will also provide additional vital information on sexual behaviour and treatment-seeking among individuals who have acknowledged engaging in or being exposed to risky sexual behaviour, since those who seek treatment are most likely to be frank about their experiences.

D6: (optional step): Making surrogate client visits to pharmacies. This is an optional step for assessing the extent and

nature of self-treatment for STDs/RTIs if earlier data collection steps have suggested this is occurring. Information about self treatment is essential for understanding local patterns of treatment-seeking, for interpreting information that is collected about patients in clinical settings, and for assessing whether antibiotic resistance of some infections as a result of inadequate or inappropriate self-treatment is likely to be a problem in the area.

E: MEDICAL STUDIES OF RTIs. This stage will provide information on the prevalence of different STDs and RTIs, both in patients seeking treatment for symptoms of these problems and in samples of the general male and female population. It will also produce information about antibiotic resistance to gonorrhoea and on patterns of treatment seeking and condom use among STD/RTI patients. Clinical and epidemiological information is essential for assessing the present extent of morbidity from STDs and RTIs and the likely risk of HIV infection in these populations.

E1: Male STD study. Clinical studies of male attenders at STD clinics will indicate which are the most common infections for which men seek treatment, where they have previously obtained treatment for such problems and their histories of exposure through high risk behaviour. Information on the prevalence of different STDs will indicate the extent to which measures to control the spread of particular infections are needed. (These measures could include appropriate clinical management strategies and provision of information on disease prevention to men in particular situations, occupations or localities). Secondly, by comparing patients' reports of symptoms with medical diagnoses based on clinical examination and with microbiological diagnoses based on laboratory testing, the best way of identifying infections reliably can be determined. Finally, data on sexual contacts and responses to experiencing symptoms will help to inform the design and content of any educational interventions for improving symptom recognition and appropriate treatment seeking in men with STDs.

E2: (optional step): Additional urethritis study. This is an optional step for gathering further information about levels of antibiotic resistance of gonorrhoea, to be carried out if resources and time permit. Additional specimens are collected from men with STD

symptoms attending clinics. This information is needed in order to adapt treatment guidelines to local conditions so that this STD is treated effectively; and to determine whether inadequate treatment is likely to increase risk of HIV transmission in those with gonococcal infection.

E3: Female RTI study. Information and specimens from female patients attending clinics for treatment of RTI symptoms can be used to estimate which infections are most common and the extent to which clinical diagnoses correlate with patients' perceptions of symptoms and with laboratory (microbiological) diagnosis. This information is needed for assessing the severity of the current situation, planning disease control strategies, and ensuring appropriate and effective clinical management of the RTIs for which women seek treatment.

E4: ANC study. In women, RTIs are often without symptoms and therefore women who come to clinics as patients presenting symptoms do not provide an accurate estimate of the amount of RTIs in the population. Antenatal clinic attenders, on the other hand, can be taken to represent a sample of the female general population because unlike other clinic attenders, they are not attending because they are unwell and also because most women are pregnant at some time in their lives. Therefore a study of antenatal clinic attenders can provide an estimate of the prevalence of infections in the population.

E5: (optional step): Additional ANC study. Antenatal clinic attenders can be taken to represent a sample of the female general population because unlike other clinic attenders, they are not unwell and because most women are pregnant at some time in their lives. This means that investigating the

prevalence of infection with Chlamydia trachomatis (CT) and Neisseria Gonorrhooea (NG) in a sample of ANC attenders can provide an estimate of the prevalence of these infections in the general population. These infections not only increase the risk of HIV transmission but also cause serious health problems in many women, including infertility. Therefore, knowing how common they are in the general population will indicate both the general potential for rapid spread of HIV transmission and whether interventions for the control and treatment of these particular infections are needed in the area.

E6: (optional step): Male general population study. STD patients and other male clinic attenders are not representative of the general male population, many of whom may not visit clinics or consider themselves to have STDs. So, in order to get an estimate of how big a problem STDs are, and therefore how rapidly HIV is likely to spread, it is necessary to study a more representative sample of the general population. This step chooses a stratified random sample from a single, large workplace where there are employees occupying a range of different socio-economic positions. A non-invasive method of collecting samples is used and useful information on general health status is fed back to the participants, while data on STDs are anonymised and kept strictly confidential. The testing kits required to analyse urine samples are expensive and the level of laboratory expertise and facilities needed is high; therefore this step should only be carried out where financial and technical resources are available. Since the results are also of considerable value in indicating levels of infection in the general population, the step should preferably be carried out at least once in each major geographical region such as a State.

Why is SASHI designed in this way?

The approaches to data collection, data recording and data analysis that are recommended in SASHI have been designed to take into account the need for speed in conducting and obtaining findings from a situational analysis and of the limited research capacity that exists in many areas. Various techniques that are used in the SASHI research protocol were selected with the intention that SASHI could be completed more rapidly than is possible in most studies, and that a team of researchers with some general background in relevant areas (clinical medicine and social science) but without any previous research experience will be able to implement SASHI successfully with appropriate training, supervision and external support.

For example, tape recording of interviews in the social science component is not advocated because tape recorders can be awkward to use and because tape recordings take a very long time to transcribe (and even longer to translate). In a rapid assessment this would take up too much of the research time which can be better used for other analysis tasks. In field testing the approach recommended, social researchers did not find tape recorders useful. Instead, simple techniques for data recording by note-taking (with instructions for writing up the information on data sheets which can be typed up afterwards into a word processor) and for hand-written completion of pre-coded forms which can be adapted for local use are described. Similarly, a very simple computer software package is recommended for analysis of the medical data that are collected, because this package is readily available and can easily be learnt with little or no training by those without experience in the use of computers or statistical packages, and because sophisticated statistical analysis is not needed for producing useful findings from the SASHI data. A computer software package is not recommended for analysis of the qualitative data collected within the social science component of SASHI, because use of such packages requires considerable technical skills and a great deal of training, which would greatly increase reliance on outside technical experts and make it impossible for a local team to analyse and utilise their own data. Instead, simple manual reading and coding techniques are recommended.

Before developing this package, the data collection methods, sample sizes, types and order of activities that are recommended in it were field tested to ensure that they are realistic and useable in a range of circumstances. This was done by piloting the complete SASHI protocol (which forms *Chapter 5* and *Appendix 5.1* of this package) in two different geographical sites in India and then thoroughly revising the protocol on the basis of these experiences and the data that were obtained. As a result of these pilot studies, it could also be seen which data collection methods and techniques were more difficult than others to carry out for a relatively inexperienced team. This informed the development of various options which can be selected according to not only the level of laboratory facilities, financial resources available and the data information needs of planners, but also according to the available technical skills of local researchers. These options are described below. However, it is important to note that all options are

planned with the assumption that some technical support will be provided by an expert Resource Group (described in next section and in *Appendix 3.1*) and such input is essential, even where the 'minimal' option is chosen for implementation, since local capacity is likely to be rather limited in such places.

Why does SASHI combine qualitative and quantitative data collection methods?

The particular data collection strategies that are set out in the SASHI protocol have been field tested, but some general principles also informed the methodological approach that was taken in designing SASHI. The use of a triangulated, multimethod approach is particularly important with respect to the collection of accurate and meaningful information. The medical components use quantitative methods, while the social science components of SASHI use qualitative methods because when investigating sensitive and personal areas of human behaviour, quantitative approaches alone are often incapable of producing valid data. For example, a door-to-door survey on people's sexual practices could use a carefully designed stratified random sampling selection technique, but the results obtained from asking people in this way would still probably be meaningless. This is because people are very unlikely to provide accurate and honest responses to a questionnaire on such personal matters that is administered by a stranger in a semi-public setting where other family members and neighbours may be listening. For exploring social and behavioural aspects of sexual health, qualitative methods of exploration are appropriate and are more likely to produce accurate findings, at least as an initial strategy for investigation. Validity and reliability of the data gathered is further enhanced when these qualitative methods are combined with or followed by the collection of quantitative (in the case of SASHI clinical and epidemiological) data. This approach of using a range of different methodological approaches is known as triangulation. It greatly enhances the likelihood of producing valid and reliable results, because data obtained about a given topic from using one method (for example, a questionnaire survey employed in a clinical setting) can be crosschecked against data on the same topic produced from using a different method, perhaps in a different but related setting (for example, a semi-structured interview in a community within the same geographical setting). In SASHI, this combination has been used for gathering information about treatment-seeking for STDs and about condom use among those practising high risk behaviour. The pilot studies demonstrated that enhanced confidence in the accuracy of the information gathered could be demonstrated where findings were consistent across both these methods.

Options for collecting data within SASHI

All steps described in *Table 1* and in *Chapter 5*, except for those which are described as 'Optional', should be carried out in any situational analysis using SASHI, so that the information which is required for intervention planning is collected. Circumstances do vary greatly from place to place though and where there are resource constraints and other limitations, it may not always be possible to conduct every step in SASHI, whereas in other circumstances, it may be necessary to carry out some or all of the optional

steps. Thus a compromise needs to be achieved between information needs and concrete circumstances.

In order to assist in deciding on the best compromise, SASHI has been divided into three main options for possible use. The 'Standard' option includes most of the steps of data collection that are summarised in *Table 1* apart from those termed 'optional' and this is the approach that should be used in most ordinary circumstances. The 'Minimal' option has a reduced range of data collection activities and should be used where human, technical and/or financial resources place serious constraints on what can be done (see Table 2 for further details on how to modify this option). The 'Comprehensive' option includes some optional steps which will provide more reliable and extensive information in circumstances when this is particularly necessary and the resources for conducting these extra steps are available. *Table 2* summarises each of the steps and stages in SASHI and indicates which of these are recommended for each option. *Appendix 2.1* provides an additional table that shows which laboratory tests would be involved within each option and the level of sophistication (in facilities and technical expertise) that is required to conduct each type of test. More details on the options within the medical component (*stage E*) of the SASHI protocol, showing which tests are required for the steps in each option and the laboratory equipment that is needed for each, are provided in *Table E1* of *Chapter* 5 (the research protocol).

Table 2: SUMMARY OF PROTOCOL SHOWING OPTIONS FOR USE

Stage & step	*Minimal version*	*Standard version*	*Comprehensive version*
A1: Existing sources of socio-economic and behavioural data	X	X	X
A2: Existing sources of epidemiological data on STDs	X	X	X
B1: Obtaining information and approval from officials	X	X	X
B2: Interviews with key informants	X	X	X
B3: Mapping sites and locations	X	X	X
B4: Mapping facilities for STD treatment	X	X	X
C1: Doing participant observation in hard-to-access populations and places	X	X	X
C2: Conducting group discussions with women		X	X
C3: Conducting group discussions with men at high risk (occupational groups)		X	x
C4: Collecting illness case histories (community based)		X	X
C5: Interviewing individuals practising high risk behaviour and members of vulnerable populations	X	X	X
D1: Making surrogate client visits to practitioners		X	X
D2: Conducting interviews and observations at pharmacies	X	X	X
D3: Conducting interviews with practitioners	X	X	X

Stage & step	*Minimal version*	*Standard version*	*Comprehensive version*
D4: Facilitating collection of patients' data by practitioners		X	X
D5: Doing exit interviews with STD patients	X	X	X
D6: Making surrogate client visits to pharmacies (optional step)			X
E1: Male STD study	X	X	X
E2: Additional Urethritis study		X	X
E3: Female RTI study	X	X	X
E4: ANC study	X	X	X
E5: Additional ANC study			X
E6: Male general population study			X

N.B. Optional steps described in this table should be included only when the situation requires (in the case of step E6); when adequate resources are available (in the case of all optional steps); and/or when the situational analysis is being carried out for the first time in a major geographical region, such as a State (in the case of step E6). See the next section and Chapter 3 for more information on the selection of options.

How and why can the SASHI protocol be modified?

Besides providing a choice between the three options shown in *Table 2*, the SASHI protocol can be adapted where necessary by leaving out or modifying specific individual data collection steps. For example, if a study that investigated the prevalence of trichomonas vaginalis (TV) infection among ante-natal clinic attenders has recently (within the past two years) been completed in the site where SASHI is to be carried out, the methods and results of this study should be assessed as part of the first stage of SASHI (within step *A2: Collection of existing data on RTIs*). If the study is found to provide reliable results that are compatible with the recommended SASHI standards and procedures for sampling and data collection, then the steps in the SASHI protocol which include investigation of TV infection could be modified to exclude this component. This modification would, in turn, allow the time and personnel resources that would otherwise have been used to do this investigation to be utilised in extra work on other components if needed.

Such modifications are particularly essential to consider for the 'Minimal' version of SASHI, since locally specific resource constraints may prevent implementation of all the steps under the 'Standard' option, but allow more than just the steps recommended in the 'Minimal' version. For example, because group discussions are time consuming to arrange

and conduct, require adequate personnel, can be difficult to facilitate and record, often work well only when researchers have considerable experience of this data collection method and the data obtained require rather careful interpretation due to group effects, they have been omitted from the 'Minimal' version of SASHI. However, imagine that in a particular site the main constraint is limited personnel on the social research team, but the few researchers who are available and able to work on SASHI already have good access to and rapport with certain vulnerable communities and ample experience in conducting group discussions. In these circumstances, it may be worthwhile to include steps *C2* and/or *C3* instead of step *B3* (and perhaps exclude step *C1*). Deciding on how to balance different steps requires a thorough knowledge of the different data collection methods advocated within SASHI and of the underlying rationale for the combinations of steps required; therefore, implementors will need to consult with members of the 'Resource Group' before modifying the protocol. *Chapter 3: Planning for SASHI* describes in more detail how to decide on which SASHI option to choose and who should be involved in making this decision.

Notes

[1] For example, in one of the pilot sites there was no concrete knowledge about whether commercial sex work was bring practised and no non-governmental organizations were working in this area. Through intensive data gathering during SASHI, information was obtained about sex work that was being practised very covertly (due to police harassment and local disapproval) in different locations and some female commercial sex workers were then identified and interviewed. It would have been impossible at the start of the study to involve either social/community workers familiar with this 'community' or sex workers themselves in carrying it out. This illustrates a situation where vulnerable populations practising high risk behaviour exist and might subsequently be involved in intervention development but are 'unknown' when SASHI is initiated. Any subsequent needs assessment or operations research could build on SASHI by approaching and involving the women who were initially identified during the situational analysis and focussing on the locations where sex work was found to occur.

[2] For example, in one of the pilot sites a particular NGO working in slum and other poor communities expressed an interest in working on the study. After discussion with the supervisors, it was agreed that the only available NGO worker did not have either sufficient time or skills to join the social research team as a member, but would work with the full time members of this team when they visited communities in her jurisdiction. Hence, the SASHI researchers were provided with valuable introductions and access through the NGO, and the NGO worker, in turn, gained new insights into the communities in which she worked by attending group discussions and new skills by learning research techniques of interviewing, social mapping etc. Conversely, in one site although the social researchers felt that their research would have been greatly facilitated either by working with an organization concerned with men who have sex with men or by having a man who identified their sexuality in this way on the research team, we were unable to identify any organization or individual having this capability in the site.

CHAPTER 3

Planning for SASHI

Introduction

This chapter describes the steps that need to be taken before implementing a situational analysis using the SASHI approach in a particular site. It sets out the preparatory activities that are required and who should carry these out, including the participants (institutions and researchers) that need to be recruited and the administrative, collaborative and other arrangements that must first be made. It also highlights the decisions that need to be taken regarding the scope of the proposed situational analysis before data collection can be initiated and sets out the criteria that need to be considered when deciding which SASHI option, in terms of the breadth and depth of coverage of the situational analysis, should be selected. An indicative timeline for SASHI from start to completion is provided at the end of this chapter *(figure 2)*. The suggestions and recommendations provided in this chapter are based on the practical experience gathered in piloting SASHI in two different locations.

Preparatory activities and the role of the Coordinator

SASHI is designed in such a way that it can be implemented by local researchers, together with the support of a group of technical experts who are referred to in this package as the 'Resource Group'. SASHI will probably be initiated by agencies such as State AIDS Societies (SASs), or Non-Governmental Organisations (NGOs) with support from the appropriate SAS. The agency intending to initiate SASHI should discuss their ideas with members of the Resource Group (RG), having identified the site for SASHI and secured the necessary budget provision (see *Appendix 3.1* for details of the types of expertise needed in the Resource Group to support planning and implementation of SASHI).

The preparatory activities described below must be carried out before SASHI can be launched. A project Coordinator must be recruited to take the lead in most of these activities, with the exception of the first step, which in some circumstances might be carried out before the Coordinator has been appointed (see 1 below).

1. Assess local institutional capacity and identify local collaborators
2. Decide on the SASHI option which is appropriate for the local setting
3. Secure formal permissions
4. Recruit research workers

5. Establish project office
6. Disseminate information on SASHI and generate a network of contacts
7. Identify local resource persons with relevant technical expertise
8. Plan ahead for the implementation phase of SASHI

1. Institutional assessment and identification of collaborators

Collaborators and partners are needed in several roles. They are needed to actually implement SASHI, with one partner providing the 'home' for the study itself and at least one other - but probably more - being the source(s) for recruitment of the research team supervisors and members. Other collaborators will be needed for facilitating SASHI, for example, by providing access to patients (medical institutions) or particular communities and settings (community-based NGOs or local health organizations). Ultimately partners will also be needed to take up and implement any further needs assessments or other studies that arise out of SASHI and any interventions that the SASHI findings indicate are needed in the site. In some cases, where the agencies initiating SASHI have sufficient capacity to carry out this task, the institutional assessment might be carried out by a senior person from this agency before the Project Coordinator for SASHI is appointed. If appropriate, the Project Coordinator could then be selected from within the institution which has been identified as the most suitable 'home' for SASHI. This approach was adopted in the SASHI pilots, when the Central Resource Group undertook institutional assessment and identified collaborators with the assistance of the initiating agencies. Otherwise, a project Coordinator should first be appointed who, in collaboration with the agencies responsible for initiating SASHI, should then assess the capacities of all potential partners - that is, local organizations and institutions - within the area where SASHI is to be undertaken. The exact identity of institutions/organizations will clearly depend on the particular SASHI site (and should also depend on information received during visits with other organizations) but is likely to include:

Local major hospitals
Local medical school
Local universities - sociology, social work, psychology, anthropology departments
Local NGOs working on sexual, reproductive and/or family health and/or social welfare
Local NGOs with active research capacity in situational assessment or other studies
State AIDS Society (if this is not the agency initiating SASHI)
Main local governmental dermatovenereology clinic
Main local governmental obstetric and gynaecology department
Main local preventive and social medicine department
Main local governmental microbiology department
Regional / national microbiology departments which may collaborate in advanced SASHI options
Local research organizations with experience in qualitative social research
Directorate of health services

Assessment will involve making visits to these organizations and institutions to meet the appropriate senior person. In most cases, this will include the Head or Director of the organization and, in the case of institutions doing academic or other research, also those staff who are active in such work. During these visits, the project coordinator (or other assessor, if undertaken by the initating agency) should explain the rationale for SASHI, elicit opinions regarding the potential usefulness of SASHI, obtain a description of the capacities of the organization, ask the head to identify the most appropriate member of the organization for liaising with the SASHI team and find out whether the organization is suitable for involvement in SASHI and is interested in taking up SASHI.

From these visits the project coordinator must compile a complete list of all potential partners that could act as the base for the SASHI team and/or from which researchers and other SASHI staff could be recruited (see point 4 below). This list will also be used in the first stage of data collection. Through these visits, it will additionally be possible to identify organizations or agencies that could potentially initiate or develop interventions for sexual health in the future after completion of SASHI. The Coordinator should also make a note of this, where appropriate, and the resulting list should be added to during the first stage of SASHI data collection. For more immediate use, from this institutional assessment and consultation with potential partners, the Coordinator should identify the most appropriate local collaborating agencies for conducting SASHI. This should include as a minimum a local dermato-venereology and a local microbiology department.

2. Decision on SASHI options to be undertaken

The SASHI coordinator will obtain information on local institutional capacity during his/her visits. This information is necessary for identifying which SASHI option - from 'minimal' to 'comprehensive', as outlined in *Table 2* in *Chapter 2* - should be undertaken. The choice of option depends upon the budget available for SASHI, the available facilities and technical resources, and the kinds of data that will be needed in order to develop an intervention strategy for the site. Certain basic elements are essential for implementing SASHI at any level; for example, office facilities and a suitable institutional base where the multidisciplinary team can meet regularly. However, many other factors, such as the size of the research team and their initial levels of expertise, can vary and a review of these factors is essential in considering how much of the SASHI protocol should be implemented.

In deciding which of the three possible options to use and also whether to modify any of the recommended steps in the SASHI protocol, the following criteria should be considered and the relevant parts of this package (indicated below) should be taken into account. The final decision on which SASHI option should be chosen and which, if any, additional modifications to the protocol are needed, should be made by the initiating agency and the

project coordinator, with detailed advisory input from the Resource Group and, when appropriate, the research team supervisors.

Criteria for selection of options:

a) ***Minimum information that is needed for deciding on and developing interventions.*** See *Chapter 1* for an overview and *Table 1* in *Chapter 2* for a summary of the kinds of data that will result from carrying out each step and stage.

b) ***Availability of skilled human resources to carry out the work under each chosen option.*** This will include three elements: field studies required for obtaining different kinds of social data, microbiological investigations for diagnosing certain infections, and the clinical expertise needed for carrying out invasive examinations and sample collection. See *Appendix 3.1* for details of the personnel requirements for SASHI and *Table E1* of the protocol in *Chapter 5* for details of both the facilities required for undertaking microbiological components, and the medical tests that are carried out for medical investigations, within each SASHI option.

c) ***Estimated budget available for essential facilities.*** See *Appendix 3.2* for essential facilities needed to conduct SASHI in order to develop an estimate based on local costs.

d) ***Estimated budget available for hiring research staff.*** See *Appendix 3.1*, which gives details of personnel requirements for various SASHI options, to develop estimates based on local salary levels for various personnel.

e) ***Estimated budget available for laboratory supplies.*** See *Appendix 3.3* for details of laboratory consumables needed to carry out the 'Standard' option of SASHI; this can be used to make an estimate of the likely expenditure on consumables for SASHI.

f) ***Overall balance.*** Between estimated total expenditure on the three components specified above (personnel, office facilities and laboratory consumables) and the total estimated budget available for implementing SASHI.

g) ***Availability of laboratory equipment and facilities required for carrying out investigations under each option and the feasibility of renewing, repairing or replacing laboratory equipment in order to ensure its proper functioning.*** See *Table E1* in *Chapter 5* for details of the laboratory procedures involved in each option and *Appendices 5.2* and *5.3* for details of the laboratory equipment and supplies needed for each option.

h) ***Time needed to complete various steps within SASHI in relation to the human resources available for carrying out research and any local time constraints***. See *Figure 2* in this chapter for an indicative timeline for each step and overall.

i) ***Scope for networking between sites*** within and between different States as a means of widening the possible range of steps that can be undertaken to generate useful data, for example by using the laboratory facilities available in another site to conduct certain tests.

j) ***Subsequent scope and political support at local and regional level for a range of possible types of health promoting intervention;*** if a broad range of intervention strategies are considered potentially acceptable, it will be more valuable and relevant to implement a more comprehensive version of the SASHI protocol, since the wider range of data collected will more reliably throw up new indications for the development of innovative but implementable strategies.

3. Securing formal permissions

Before commencing SASHI, the Project Coordinator must obtain written approval from governmental agencies, following guidance and assistance from the State AIDS Society. Such permission should be sought from the health ministry (at State level), from the Director of health services and from the municipal corporation. The appropriate governmental agencies should be asked to produce identification and authorisation documents for each research worker that they can present if requested to do so during data collection activities.

4. Recruitment of research workers

The Project Coordinator should have primary responsibility for recruiting the teams of research workers required for conducting SASHI. The core SASHI research group consists of two teams — a social science team and a medical team. A supervisor is required for each of these teams and the identification of these supervisors should be made before the rest of the teams are recruited. The social science supervisor should have an appropriate postgraduate qualification, experience of social science research or community work and knowledge of qualitative research methods. The medical supervisor should be an experienced MBBS, preferably with a postgraduate epidemiological degree and some research background, with experience of team management. Once recruited, these supervisors should take the lead in recruiting the rest of their research team with assistance from the Coordinator as necessary. Staffing requirements for SASHI research teams are given in *Appendix 3.1*. Recruitment of social science researchers is likely to be from local university departments (social work, sociology, anthropology, psychology), NGOs or

possibly private research organizations; if resources permit, members of a suitable social research agency can be contracted for this purpose. Medical researchers are likely to come from local medical schools, government facilities (such as civil or district hospitals) or research institutes.

5. Establishing a project office

The Project Coordinator should identify a local project office and secure the use of this facility. The office should have a telephone, meeting facilities and a room where the project computer could be safely located. The office could be in the medical school, university, State AIDS society or a NGO. Failing this, commercial premises could be rented. *Appendix 3.2* provides further details of the requirements for the project office.

6. Dissemination information on SASHI and establishing a network of contacts

Once the project office has been established, collaborators identified and the supervisors of the research teams contracted, the Project Coordinator should draw up a simple (1-2 page) written description of SASHI that gives an outline of what activities will be carried out and contact details of the initiating agency, implementing institution/organization, Coordinator and research supervisors. The coordinator or research team supervisors should distribute this briefing document to all local agencies. Distribution of this document will provide an opportunity to build on the network of contacts made during the initial institutional assessment visits and to confirm that preparations for SASHI are in place. Additional copies should be made available to each member of research teams to keep with them once data collection starts, so that they can be provided to any interested persons.

7. Planning for the implementation phase of SASHI

Active data collection phases in SASHI need to be carefully reviewed before training of the research teams starts, so as to make sure that the necessary supplies, permissions and other pre-requisites are in place before the start of the implementation phase. A timeline is provided below in order to give a rough estimate of the length of time that each data collection step in SASHI is expected to take, although of course this will vary depending on local conditions. This timeline should also be consulted in considering which SASHI option to choose, and in planning the training programme for the research team and supervisory arrangements (covered in the next chapter).

Figure 2: Timeline for SASHI implementation

SASHI step		Before start of data collection	Training period and pilot week	Month 1	Month 2	Month 3	After end of data collection
Weeks (X = 1 week)							
0.1	Getting permissions	XX	XX				
0.2	Support creation	XXXX	XXX	X X			
0.3	Training		XXX				
A1	Existing sources (social science)			XXXX	x x	x x	
A2	Existing sources (epidemiological)			XXXX	x x	x x	
B1	Obtaining information & authorisation	XXXX		XXX			
B2	Interviews with key informants			XXXX	x x	x x	
B3	Mapping sites and locations			XX	XX		
B4	Mapping treatment providers			XX	XXXX	x x	
C1	Doing Participant observation			XXX	XXXX	x x	
C2	Group discussions (women)				XX	XX	
C3	Group discussions (high risk men)				XXX	X x	
C4	Illness case history collection				x X	XX x	
C5	Interviews with those at high risk				X XX X	X x x	
D1	Surrogate client visits to practitioners				X X X		
D2	Interviews & observations at pharmacies			XXX	x x		
D3	Interviews with practitioners				x XX	X x x	
D4	Data collection by treatment providers				x	XXXX	
D5	Patient exit interviews			x x	x XXX	x x	
E1	Study of STDs in men			XXX	XXXX	xx	
E2	Urethritis study				x x X	XXXX	

SASHI step	Before start of data collection	Training period and pilot week	Month 1	Month 2	Month 3	After end of data collection
E3 Study of RTIs in women			XXXX	XXXX	XXX	
E4 Study of ANC attenders			XXXX	XXXX	XXX	
E5 Additional ANC study				X	XXXX	
E6 Male general population study				XX	XXX	
Data analysis and report writing			X	XXX	XXX	XXXX

KEY

XXX Intensive data collection (one cross equals one week)

x x x Ongoing or intermittent data collection, start and finish dates depend upon completion of earlier studies

CHAPTER 4

Training for SASHI

Introduction

This chapter describes the kinds of training which are needed in order to carry out SASHI, who should provide and participate in it and the preparatory steps that should be undertaken. A model training timetable which can be adapted for local use is provided. Modifications should be made in consultation with resource persons who are familiar with SASHI and can provide more direct guidance.

Training needs in SASHI

The SASHI protocol is designed for use by a team which has undergone training by a core Resource Group of experienced facilitators and other resource persons as suggested in this chapter and which also has access to on-going technical guidance from the Resource Group, as described in Appendix 3.1.

Before commencing SASHI, the local research team should be oriented to the conceptual framework and objectives of SASHI and should also be trained in the use of appropriate data collection methods and techniques. It is essential for the team to gain familiarity with the key sociological and medical concepts related to SASHI such as sexual health, sexuality, high-risk sexual behaviour, STDs, HIV/AIDS and other similar concepts and terms. Therefore, the initial period during training should be devoted to explicating these relevant concepts and terms and bringing out their sociological, anthropological, clinical, epidemiological and ethical dimensions. Developing an understanding of the conceptual base of SASHI, namely, the multidisciplinary approach to assessing sexual health, should be an essential part of the training. To this end, the training programme should emphasise the need for dovetailing the medical and social research components through practical exercises.

It is important to adapt the programme outlined here to local needs and circumstances. It is also possible to condense the training period where the local teams already have some expertise in the relevant areas or where resources and time are very limited. Such modifications should, however, be made in consultation with resource persons who are familiar with SASHI and can advise on which components of the training can be condensed, omitted, or covered alternatively through detailed feedback and guidance during early stages of data collection.

Components, duration and location of training

Training for SASHI overall will include the following components:

(a) Preparation for Training Programme (2 days)

Two days will be needed before the start of training so that those responsible for the training can prepare and organise the programme. This should be done at least one month prior to the start of the main training period, in order to allow time for local experts and other resource persons who will participate in the training (see below) to be invited.

(b) Orientation for Co-ordinator and Team Supervisors (1 day)

The training period should start with a one-day orientation session, conducted by the Resource Group exclusively for the Local Co-ordinator and the Social Science and Medical Supervisors, that precedes the main training programme. The purpose of this informal session should be to generally familiarise these lead persons with the SASHI approach and protocol and to orient them to the nature of supervision required in SASHI, discuss areas requiring co-ordination between the teams and understand the importance of frequent interaction between the social and medical research teams during the process of data collection.

(c) Main Training Programme (10 days)

The main training period should be spread over ten days after the full research team has been recruited and all institutional links established. The methodology for training both medical and social researchers should comprise classroom lectures, small work-group sessions, role-plays, mock/demonstration sessions and field visits. A model training programme for this period is provided at the end of the chapter together with introductory exercises that can be used at the start of the programme.

(d) Piloting Period (5 days)

The ten-day formal training period should be followed by a week-long pilot period of actual data collection in field sites (clinics and communities). During this period, real data are collected in genuine conditions but these are used for the purpose of familiarising the researchers with actual data collection process and in the case of the medical team, all data collected during this period are discarded and not included in the final data set. A gap of two days is recommended at the end of the training period and before the start of the pilot, for the research staff to re-read the protocol carefully having completed their training.

The venue of SASHI training should be selected on the basis of availability of the resources needed for SASHI, including access to a laboratory. The Dermatovenereology or the Microbiology Departments in a medical college hospital may be suitable venues given the accessibility to laboratories and clinical (outpatient) settings. However, where there is a lack of facilities for the team to meet together as a group without danger of disruption or interruption in such settings, the classroom components of the training programme could be conducted at a separate - but not too distant - place from the clinical and laboratory based components.

Participants and approaches in the training programme

The main training programme must be organised and facilitated by the local SASHI coordinator together with a group of resource persons (referred to below as the 'resource group' or RG) who are familiar with the SASHI approach and rapid assessment procedures. This group must include at least one technical expert in each of the main disciplinary elements of SASHI - that is, clinical epidemiology, microbiology and qualitative social science (usually sociology or anthropology) - some or all of whom also have experience of conducting research on sexual health and STDs. In addition, wherever possible local experts with research experience in the area and good communication skills (referred to below as 'Regional Resource Persons', 'RRP') should be invited to take some training sessions. For instance, in one of the pilot sites a local STD specialist was invited to present the session on medical aspects of STDs and HIV/AIDS. Likewise a local social science researcher who had conducted research on female commercial sex workers, presented her work in relation to 'Researching sensitive subjects' and facilitated a team visit to the local red-light area. Local or regional experts should be invited to take sessions on relevant topics on which they are particularly knowledgeable, such as the State AIDS Officer, who could introduce the training programme with a presentation on sexual health in the region with a particular focus on HIV epidemiology and/or an overview of the HIV prevention and sexual health promotion initiatives that are currently in place or under development.

The training programme should be attended by all SASHI staff including the local co-ordinator and social and medical team supervisors. The person who will be responsible for data entry and analysis in the SASHI project (data entry operator, as described in Appendix 3.1) should also go through the training and simultaneously create data-entry files using the statistical package EPI-INFO for the mock medical data and sample collection exercise during the second week of training. This person should also give feedback during this training exercise on gaps and inconsistencies in data collection, which, if taken note of, will assure a better performance throughout the project.

Prior to, or during the first week of the training period, the two laboratory technicians selected to work on SASHI will be trained in conducting all the tests that are to be undertaken at an appropriate centre of expertise. As far as possible the bulk of the laboratory training should be carried out at the facilities which will be involved in SASHI so that difficulties encountered can be anticipated and overcome prior to starting SASHI. Tests which are not, at the time of identifying sites, usually performed at the laboratory that will participate in SASHI, should, if possible, be established at this laboratory by sending the SASHI microbiologist for training in these tests elsewhere, after which they should then set up the tests locally. If particular laboratory facilities are lacking at the SASHI site and certain tests cannot be performed there then training for these tests should be given at the centre at which the tests will be performed. In this case it is likely that person with laboratory expertise will need to be recruited at this centre. In the second week of the training the laboratory technicians should give feed back to the medical researchers on aspects of sample collection, storage and transportation procedures that could influence the laboratory test results.

Clinical data and samples collected during the training period will be utilised solely for standardizing the sample collection and microbiological methods. They will not be included in the analysed data set.

In order to ensure and facilitate coordination between the medical and social science teams periodic joint interactive sessions should be arranged at least three times during the training. These joint sessions should be designed to help researchers identify areas of mutual importance to the two teams, the skills in taking leads from each team's ongoing data collection and to generally share and exchange notes with a view to facilitate further data collection.

Local coordinators and supervisors should take a central role in facilitating and leading the training, especially as they become increasingly familiarised with SASHI. The programme should be reviewed during the initial two-day orientation session for supervisors, modified as necessary, and appropriate tasks for leading and facilitating sessions agreed between the supervisors and resource persons.

Model training programme for SASHI

Two introductory exercises given below can be used at the start of the main training programme (component (c) above). SASHI deals with highly personal and sensitive topics, such as sex and sexuality. It is important that researchers collecting data on such subjects be comfortable working with each other, sometimes in a mixed team, and be aware of and oriented to the complexity of the subject. To facilitate this, the introductory session should be an ice-breaking session (Example 1 below) instead of a formal introduction. A subsequent session should comprise an exercise orienting the researchers to the complex and taboo topics of sex and sexuality (Example 2 below). This may encourage them to overcome personal inhibitions of talking about sex to respondents, explore the vocabulary used locally, and get acquainted with alternative sexualities. These examples should be built into a full training programme. A model example of such a programme for the main 10-day training period which includes these exercises is provided at the end of the chapter. This can be adapted for local use.

Exercise 1: Ice-Breaking Session

Purpose:

To help group members introduce each other in an informal manner and get to know each other better.

What you need:

Pen, paper, one bowl, chairs along the walls to have some space to move around freely. Time- about 30 minutes.

What you do:

1. Make as many small paper chits as there are members in the group.

2. Draw pairs of geometrical figures/shapes (e.g. O, +, Ñ, Ä, ´) on the chits such that each shape is drawn once on each of two chits.

3. Make everybody sit around in a circle and go around the circle with the chits in a bowl. Let each member pick one chit.

4. Ask the members to find the other member in the room who has a chit with the same figure/shape as them.

5. Once all the members have located their partners in this manner, they should gather the following information about each other: name, professional qualification and experience, family life, hobbies and interests. Write this list up on a chalk board or chart paper where it can be seen for all to refer to. Time limit for this activity is 5 minutes.

6. Call the group to order. Ask each member to introduce his/her partner to the group based on the information gathered. Encourage them to give the information in an interesting manner.

Outcome:

This exercise makes people move around and open up as it encourages them to learn more about each other. It breaks the ice and builds warmth in the group.

Exercise 2: Talking about sex

Purpose:

To recognise the inhibitions and embarrassment associated with topics related to sex and try to overcome them.

What you need:

Pen, sheets of paper, several copies of lists of 10 English words with a sexual connotation (e.g. breast, masturbate, vagina, sexual intercourse, ejaculation). If English is not a familiar language to the members, provide lists of regional language words.

What you do:

1. Divide the group into smaller groups of 5-6 members each. Make some groups more heterogeneous than others. (For example, some groups should contain people of the same gender and similar with respect to age and professional qualifications. One or two groups should be more mixed).

2. Provide each group with a pen and the list of words related to sex (in English or the regional language).

3. Ask each group to think of and record as many local/colloquial words for each of the words as possible. Encourage them to discuss the words in the group. Give 15 minutes to each group.

4. Call the groups back into the main group. Pose the following questions:

— How many colloquial words were each group able to write for the given words?

(This will tell them about their adequate/inadequate familiarity with the local language words on sex.)

— How did members feel using/speaking these words?

(This will help the members to acknowledge their comfort/discomfort about such words.)

— Which groups had more difficulty in performing this activity and why?

(Usually homogenous groups comprising same sex/age/professional backgrounds find it easier to do this activity because of their shared understandings.)

Outcome:

This exercise helps members to come face to face with their hang-ups on sex and to consider ways of overcoming them.

Model training programme for SASHI

VENUE: A local institution in which SASHI is located

- All material (e.g. overhead projector, slide projector) and administrative requirements (e.g. permissions for use of space, etc.) must be put in place/checked for availability at least 2 days prior to the onset of the training programme.

- Invitations issued to the local key people and representatives of possible collaborating agencies must be confirmed for the introductory programme on the first day.

- Provision of all minor or major supplies and equipment required to carry out tests should be checked during the preparatory phase. Provision of a standard medical laboratory technology book and other published articles for reference must be procured in advance.

PREPARATORY PHASE (1 day) for Orientation of Co-ordinator and Team Supervisors.

Participants:

1. Resource Group (RG)
2. Co-ordinator
3. Medical and Social Supervisors

MAIN TRAINING PROGRAMME for full research team (10 DAYS)

Participants

1. Resource Group (RG): About 4 researchers with backgrounds in Community or Public Health, Psychology, Sociology, Social Work, Social/Medical Anthropology, Epidemiology who are familiar with conducting SASHI and in using rapid assessment procedures in the field of sexual health.
2. Regional Resource Persons (RRP): Programme Officer of the State AIDS Society, other local/regional experts including Dermato-venereologist, Social Science Researchers.
3. Co-ordinator (1).
4. Social Science Team: 1 Social Science Supervisor, 6 Field Researchers.
5. Medical Team: 1 Medical Supervisor, 6 Medical Researchers, 1 Microbiologist, 1-2 Laboratory Technicians, 1 Peon/Laboratory Assistant.
6. Data entry clerk/Administrative and secretarial assistant to SASHI team.
7. Statistician or epidemiologist (part-time, where available).

Note: This training programme is designed to involve active, participatory learning. For many sessions and particularly those which involve reviewing of previous exercises or discussion, all participants should take an active part; those designated as 'Facilitator/ Trainer' will facilitate participation from trainees rather than present material or views themselves. Local/regional resource persons (RRG) and members of the Resource Group (RG) are not indicated specifically in the programme but their participation in particular sessions would relate to their expertise in that area. Thus the medical team will be trained by members of the RG who have skills and expertise in clinical epidemiology, while the social science team will be trained by members of the RG with social science expertise.

Table 1: Model Training Programme for SASHI team

Date	Time	Topic / Issue	Facilitator / Trainer
Day 1	09.45 - 10.00	Welcome and introduction to the orientation workshop	RG and RRP
	10.00 - 10.30	Overview of the ongoing work on sexual health in the region	Programme Manager of SAS
	10.30 - 11.00	Tea break	
	11.00 - 12.00	Introduction to SASHI Project, orientation to SASHI philosophy and conceptual framework	RG
	12.00 - 13.00	Introduction of participants and resource persons (Exercise 1)	RG and SASHI Co-ordinator
	13.00- 14.00	Lunch	
	14.00 - 16.00	Overview : STDs/AIDS with special reference to epidemiology in the region	RG or local STD expert
	16.00 - 17.30	Orientation to SASHI concepts, with examples	RG
Day 2	9.00 –10.30	Orientation on Sexuality and Sexual Health : Medical and Social Aspects	RG
	10.30-11.00	Tea break	
	11.00 – 13.00	Session Continues.	
	13.00 – 14.00	Lunch	
	14.00 – 17.00	Research on sensitive issues: guiding philosophy, key principles, exploring one's own attitudes to sex and sexuality, talking about sexuality (including Exercise 2).	RG

From now on, social science and medical teams continue most of their training in separate sessions, but will meet during plenary (joint) sessions.

Date	Time	Topic/ Issue (Social Science Team)	Facilitator/ Trainer	Time	Topic/ Issue (Medical Team)	Facilitator/ Trainer
Day 3	09.00 - 09.20	Plenary session: Summary of previous day	RG /RRP	09.00 - 09.20	[as for Social Science team]	
	09.20 - 10.30	Ethical issues in social science research	RG	09.20 - 10.30	Detailed objectives of SASHI, roles and tasks of the medical team; brainstorming on data needs	RG
	10.30 -11.00	Tea Break		10.30 - 11.00	Tea Break	RG
	11.00 - 13.00	Detailed objectives of SASHI : Expected outcomes, roles and tasks of the social research team	RG	11.00 - 12.00	Discussion: how can these data be obtained?	
		session continues	RG and RRP	12.00-13.00	STD / gynae. Clinic based study: rationale, questionnaires, data collection sheets	RG
	13.00-14.00	Lunch Break		13.00-14.00	Lunch Break	RG
	14.00 – 17.00	Discussion : Which data do we need and how can they be obtained		14.00-15.30	How to collect specimens	
	15.30-16.00	Tea Break		15.30-16.00	Tea Break	
	16.00-17.00	Discussion on data needs continues		16.00-17.00	How to obtain informed consent; How to collaborate with clinic doctors and staff	RG/RRP
	17.00-17.30	Plenary sessions– sharing information of day 3	RG/RRP	17.00 - 17.30	[as for Social Science team]	

Date	Time	Topic/ Issue (Social Science Team)	Facilitator/ Trainer	Time	Topic/ Issue (Medical Team)	Facilitator/ Trainer
Day 4	09.00 – 10.30	Mapping the site: semistructured interviews with key informants	RG	09.00 - 09.30	Summary of previous day; task for day 4	RG/RRP
	10.30 – 11.30	As above: demonstration interview	RG	09.30 - 10.30	Mock exercises with STD/ gynae study questionnaire and data recording forms	RG/RRP
	11.30 – 1300	Mapping the site: Observation	RG	10.30 - 13.00	Visit STD clinic, practical exercises on specimen and data collection	RG/RRP
	13.00 – 14.00	Lunch break		13.00 - 14.00	Lunch break	
	14.00 – 17.00	Field visit for practical exercise in site mapping	RG/RRP	14.00 - 15.15	Review of practical exercises	RG/RRP
		Field visit continues		15.15-15.45	Tea Break	
		Field visit continues		15.45-17.30	ANC study: rationale, design, questionnaires and mock exercises. Includes session on sampling of study population	RG/RRP
Day 5	09.00 – 9.30	Summary of previous day; tasks for day 5	RG	09.00 - 09.30	Summary of previous day; task for day 5	RG/RRP
	09.30 - 11.30	Studying sexual health behaviour : Community based group discussions (FGD, access routes to various vulnerable groups, problems and adaptations)	RG with RRP	09.30 - 10.15	How to collect ANC specimens	RG/RRP

Date	Time	Topic/ Issue (Social Science Team)	Facilitator/ Trainer	Time	Topic/ Issue (Medical Team)	Facilitator/ Trainer
	11.30 - 13.00	Studying sexual and health behaviour: participatory mapping		10.15 –13.00	Visit ANC clinic: demonstration and exercises on data and specimen collection	RG/RRP
	13.00-14.00	Lunch break		13.00 - 14.00	Lunch break	
	14.00 - 17.30	Field visit to practice & demonstrate FGD, participatory mapping		14.00 –15.00	Review of practical exercises at ANC clinic	RG/RRP
				15.00 - 15.30	Tea break	
		Field visit continues		15.30 - 17.00	Male general population study: rationale, design, questionnaires and mock exercises	RG
Day 6	09.00 - 9.30	Summary of previous day; tasks for day 6	All	09.00 - 09.30	Summary of previous day; task for day 6	RG/RRP
	09.30 - 11.30	Studying sexual and health behaviour: In-depth interviews Case histories	RG	09.30 - 10.00	Review of STD/ gynae clinic study	RG/RRP
	11.30 - 13.00	As above with mock interviews and demonstration	RG	10.00 - 13.00	Visit gynae clinic; demonstration and exercises on data and specimen collection	RG/RRP
	13.00 – 14.00	Lunch		13.00 - 14.00	Lunch	
	14.00 - 16.00	Plenary session: medical /social teams report activities; discuss coordination between 2 teams; break into small	RG and RRP	14.00 - 16.00	[as for social science team]	

Date	Time	Topic/ Issue (Social Science Team)	Facilitator/ Trainer	Time	Topic/ Issue (Medical Team)	Facilitator/ Trainer
		mixed-team groups to discuss information needs and approaches to data collection (team members give presentations of their approaches). Discussion on ethics, exchange of information, value of sharing for further data collection.				
	16.00 - 17.00	Supervisory arrangements within and between teams	Social supervisor; RG		Supervisory arrangements within and between teams	Medical supervisor; RG
Day 7	09.00 - 09.30	Summary of previous day; tasks for day 7	RRP	09.00 - 09.30	Summary of previous day; tasks for day 7	RG/RRP
	09.30 - 10.30	Studying STD/ RTI services: exit interviews with patients		09.30 - 10.30	Review of STD clinic study	RG/RRP
	10.30 - 13.00	Joint visit to STD clinic; observe, make notes on and conduct exit interviews under supervision	RG	10.30 - 13.00	Visit STD clinic: Collect specimens and complete data sheets under supervision; conduct exit interviews under social science supervision	RG/RRP
	13.00 - 14.00	Lunch	RG	13.00 - 14.00	Lunch	
	14.00 - 15.00	Joint review of STD clinic visit, note-taking, specimen collection and data recording	RG, medical and social supervisors	14.00 - 15.00	[as for social science team]	

Date	Time	Topic/ Issue (Social Science Team)	Facilitator/ Trainer	Time	Topic/ Issue (Medical Team)	Facilitator/ Trainer
	15.00 - 15.30	Tea break	RG and RRP	15.00 - 15.30	Tea break	
	15.30 – 17.30	Studying STD/ RTI services: interviews with health providers, with demos	RG and RRP	15.30 - 17.30	[as for social science team]	
Day 8	09.00 - 09.30	Review of previous day; tasks for day 8	RG and RRP	09.00 - 09.30	Review of previous day; tasks for day 8	RRP
	09.30 - 10.45	Studying high risk behaviour in the region	Invited presentation	09.30 - 10.00	Review of ANC study	RG/RRP
	10.45 - 14.00	Field visit to a red light area, with demonstrations & practice in informal interviews with sex workers & private health providers	RG with NGO/RRP	10.00 - 13.00	Visit ANC clinic; medical fieldworkers to collect specimens and complete data sheets under supervision	RG/RRP
	14.00 - 15.00	Lunch		13.00 - 14.00	Lunch	
	15.00 – 16.00	Review of field visit, interview techniques and recording of data		14.00 - 15.00	Review of ANC study visit and specimen collection/ data sheets	RRP/RG
	16.00 - 16.15	Tea break		15.00 - 15.30	Tea break	
	16.15 - 17.30	Review of data collection techniques in small groups, with case illustrations of KIIs/ FGDs/Mapping		15.30 - 16.30	Additional urethritis study and ANC study: rationale, design	RG/RRP
				16.30 - 17.30	Collaboration with microbiology department	Head of Microbiology Dept; SASHI microbiologist

Date	Time	Topic/ Issue (Social Science Team)	Facilitator/ Trainer	Time	Topic/ Issue (Medical Team)	Facilitator/ Trainer
Day 9	09.00 – 9.30	Review of previous day; tasks for day 9	RRP with all	09.00 - 09.30	Review of previous day; tasks for day 9	RRG
	09.30 - 11.00	Data recording: Taking field notes, maintaining activity log, writing up and coding data recording forms	RG with RRP	09.30 - 10.45	Routine data collection; rationale and methods; Review of all studies	RG/RRP
	11.00 - 11.15	Tea break		10.45 - 11.00	Tea break	
	11.15 - 13.00	Working with the SASHI Protocol		11.00 - 12.00	Collection of consultation data from private dermato-venereologists: rationale, methods & mock exercise	RG
				12.00 - 13.00	Data entry and analysis, with demonstration of Epi-Info	RG/data entry personnel
	13.00 - 14.00	Lunch		13.00 - 14.00	Lunch	
	14.00 - 15.30	Working with the SASHI Protocol (contd.)		14.00 - 15.15	Use of SASHI laboratory results in patient management	Head of STD & gynae-cology Depts; RG
	15.30 - 15.45	Tea break		15.15 - 15.45	Tea break	
	15.45 - 17.00	Data analysis: Initial coding, how to identify themes, develop links; uses in report writing		15.45 - 17.00	Using data analysis for report writing	RG
Day 10	09.00 - 9.30	Review of previous day: tasks for day 10	RG	09.00 - 09.30	Review of previous day; tasks for day 10	RRP

Date	Time	Topic/ Issue (Social Science Team)	Facilitator/ Trainer	Time	Topic/ Issue (Medical Team)	Facilitator/ Trainer
	09.30 - 11.00	Planning for pilot week, division of responsibilities, preparation of timetable	RG and RRP	09.30 - 10.30	Planning for pilot week; division of responsibilities and timetable	RRP
	11.00 - 13.00	Using data analysis to decide next steps in data collection; weekly team meetings and planning of ongoing research		10.30 - 13.00	Divide up into small groups and visit STD, ANC and gynae clinics under supervision for full specimen collection and data form completion pilots	All
	13.00 - 14.00	Lunch		13.00 - 14.00	Lunch	
	14.00 - 15.15	Review of field visits, identification of potential problems		14.00 - 15.15	Review of clinic visits; identification of problems	RRP/RG
	15.15 - 15.45	Tea		15.15 - 15.45	Tea	
	15.45 - 16.30	Review of training	RG	15.45 - 16.30	Review of training	RG
	16.30 - 17.30	Plenary: Coordination between teams on taking and giving leads during pilot week		16.30 - 17.30	[as for Social Science team]	
	18.00 - 20.00	Steering group meeting	(RG, Co-ordinator, Supervisors)	18.00 - 20.00	[as for Social Science team]	

The training period will continue after a 2-day break, followed by:
One-week pilot study after which SASHI data collection proper commences.

CHAPTER 5

Situational Analysis of Sexual Health in India (SASHI) Protocol

Introduction

This chapter sets out the SASHI protocol which describes the precise components and procedures for collection of data during the situational analysis. It includes details of the methods to be utilised, the kinds of data to be gathered, the appropriate techniques for taking clinical samples and the settings and sources from which information should be collected. It provides detailed and exact instructions about each component of data collection and it is, therefore, essential that it is studied and used carefully by each member of the SASHI research team. Guides and forms for data collection and recording and other procedural guidelines and checklists related to the protocol are provided in the Appendices to this chapter. This protocol and the data recording forms, data collection guides and checklists that make up the Appendices are also available in disk format, so that they can be reproduced, reprinted and modified as needed.

Format

The protocol is divided into lettered stages (marked A, B, C, D and E in **bold**) that designate different phases of the data collection process. These stages are subdivided into numbered steps (1, 2, 3 and so on in **bold**), which describe exactly which data collection activities should be carried out. Details of appropriate sample sizes, selection of informants or data sources, topics to be covered, data collection procedures and order of activities are all specified precisely for each data collection step.

Many of these steps use specific tools for data collection that are provided in *Appendix 5.1*, such as recording forms, topic guides and questionnaires. Each of these tools is numbered according to the stage letter and step number for which it should be used (e.g. **C2, D1**) and the tool or tools which should be used for each step are indicated in the main text *in italics*. The main text of the protocol also specifies who should undertake different data collection steps. For example, most steps in stages B and C are carried out by social researchers in the SASHI team and all of the activities in stage E are carried out by medical researchers, while stage A and some steps in stages B and D are carried out by members of both teams. All other Appendices and parts of the package that contain essential information for implementing SASHI are referred to in the text *in italics*.

Aims

The overall aim of SASHI is to collect information that is necessary for prioritising and designing interventions for promoting sexual health, in particular effective control and prevention of sexually transmitted diseases (STDs), reproductive tract infections (RTIs) and HIV/AIDS. This involves collection of both medical (clinical, epidemiological and microbiological) and social science (sociological, anthropological and behavioural) information. This information could, in principle, also contribute to the baseline data required for the monitoring of sexual health and its determinants and the evaluation of intervention projects.

Objectives

1. To identify local stakeholders and opinion leaders with potential interest in sexual health-related projects
2. To determine the patterns of high risk sexual behaviour
3. To identify populations who are particularly vulnerable to STDs/RTIs and HIV infection
4. To ascertain perceptions of risk for STDs/RTIs and HIV/AIDS among potentially vulnerable local populations
5. To describe local perceptions of the nature, prevention and causes of STDs/RTIs and HIV/AIDS
6. To identify situations, contexts, times and locales in which risky sexual behaviour occurs
7. To locate locally used sources of treatment for STDs/RTIs
8. To determine the nature and quality of care provided for STDs/RTIs by treatment providers
9. To identify patterns of treatment-seeking for STDs/RTIs
10. To determine the prevalence of important STDs/RTIs in the general population
11. To determine the aetiology and prevalence of STDs among STD patients
12. To identify patterns of antibiotic resistance in STD patients with gonorrhoea

STAGE A: COMPILATION OF EXISTING DATA

Purpose: To identify relevant available knowledge which subsequent stages can build on.

Activities:

— collect all existing information on the reproductive and sexual health and socio-demographic characteristics of the populations in the geographical site

— obtain and prepare a bibliography of available research literature and relevant published and unpublished reports and quantitative data

— compile a list of contact details of individuals and NGOs who can provide further useful information

This stage will be carried out by members of both the social science and medical teams. Relevant findings will include summaries of data directly concerning sexual health; for example, prevalence of syphilis among pregnant women as recorded by antenatal clinics which conduct VDRL testing. It will also include information which might be helpful in directing subsequent stages of the study, such as selection of areas or populations in the study site where high risk behaviour may be occurring (for example as indicated by high rates of unmarried pregnancy or reproductive tract infections, or particularly poor working conditions or high mobility rates which are likely to make the populations affected by them especially vulnerable).

A1: Collecting existing socio-economic and behavioural data

This step will be carried out by the social science supervisor with assistance from other members of the social science team.

— Visit all University postgraduate sociology, demography, psychology, anthropology and women's studies departments and other centres and all social science and population research institutions to collect existing reports and information on STDs/RTIs, HIV, reproductive health or treatment-seeking behaviour, sexuality and sexual health, or on potentially vulnerable populations in the area such as sex workers and migrant labourers. Also interview relevant faculty from these institutions and departments to understand local context and issues, and to ascertain who else outside the faculty has conducted other relevant studies.

— Contact Non-Governmental Organization (NGOs) working on various aspects of health, fertility, sexual health, HIV/AIDS, family welfare or women's status in the area and any other social scientists for reports and information relevant to SASHI (as above).

— Collect reports on the socio-economic and demographic profiles of the areas from State and District authorities, including the National Health and Fertility Survey (NHFS) for the State and District Census Handbooks.

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— To the initial list of potential collaborators and partners already compiled by the SASHI Coordinator, add details of any further institutions or agencies that have been identified incidentally as a result of this data collection step, as potentially suitable for taking up sexual health interventions after completion of SASHI, if needed.

A2: Collecting existing epidemiological data on STDs and RTIs

This step will be carried out personally by the medical supervisor who will:

— Communicate with the State AIDS Cell officer and obtain copies of epidemiological data on STDs and RTIs kept by SAC. Information on the cumulative number of AIDS dignoses and results of HIV tests carried out in the State (including sentinel surveillance, blood bank, clinical tests, dermatovenereology clinics) should be collected. With respect to HIV tests it is important to obtain both numerators and denominators and if possible, the socio-demographic, medical and behavioural characteristics of those tested. Ask the SAC officer for names of other institutions in the State or nationally that may have more detailed data (e.g. in some sites there will be specific AIDS/HIV surveillance centres) and for any specific STD or AIDS/HIV studies - published or unpublished - done in the State. If there are any such studies, try to obtain the results. Obtain photocopies or reports of data sources wherever possible, rather than having handwritten notes transcribed from the original as the only record. Also interview staff of the SAC in detail about the current situation regarding HIV infection in the State in general and the SASHI site in particular.

— Carry out interviews on the above topics in the study area with the appropriate responsible officer within the Directorate of Health Services and the Public Health Department.

— Visit any blood bank in the study site and obtain data regarding HIV and VDRL tests. If donor category data (voluntary, replacement and professional) are available, these should be recorded. Interview the responsible officer regarding other blood banks in the area; ask for suggestions as to other data sources which have not yet been accessed and for their perceptions of the current status of HIV infection in the area.

— Visit each public sector dermatovenereological clinic in the SASHI site. These should have records of cases seen over the past several years, athough the quality (and even availability) of information is highly variable between clinics. This information should be, but often is not, reported centrally to NACO. Within each public sector dermatovenerological clinic the level of detail in which the data are kept varies. If possible, abstract the following and in the case of test results make sure to record and describe the denominator and the criteria for doing testing:

  ★ number of new cases of the different STDs (at finest available level of disaggregation)

  ★ number of return visits for follow-up

- ★ demographic data on such cases - gender at least should be recorded
- ★ antibiotic sensitivity reports in the case of gonorrhoea
- ★ number of HIV tests performed, number of these which were positive and criteria for doing HIV testing
- ★ number of VDRL tests performed, and number of these which were positive, together with dilution data (number positive at dilutions greater than 1 in 8 if these are collected) and criteria for doing VDRL testing

— Visit public and private antenatal clinics in the study area and record the number and results of VDRL tests performed (as above). Record any information on the coverage of the antenatal clinic (i.e. percentage of pregnant women in the area who make use of antenatal services, demographic and socio-economic characteristics of the clientele served). Visit both public and private clinics.

— Visit Microbiology and, if necessary, Pathology department laboratories of all government hospitals and a feasible sample of private labs (at least 5 in an urban site) to record reports of VDRL tests, HIV tests, gonorrhoea cultures and antibiotic sensitivities, and other tests relating to STIs mentioned by the laboratory staff.

— Enquire about any studies of STDs or RTIs within the study area during all the above visits and with any other key informants. If such studies are identified make strenuous efforts to obtain the reports. If no reports exist or the reports are inadequate, carry out direct interviews with the researchers who conducted the studies.

— To the initial list of potential collaborators and partners already compiled by the SASHI Coordinator, add details of any further institutions or agencies that have been identified incidentally as a result of this data collection step as potentially suitable for taking up sexual health interventions after completion of SASHI, if needed.

STAGE B: SITE MAPPING

Purpose: To gather information about localities and places associated with high risk sexual behaviour (henceforth 'HRB') and where people obtain treatment for STDs and RTIs and to present this information in the form of a map. Also to identify individuals from whom more detailed information needs to be collected, to locate places requiring further investigation and to identify agencies to whom informants may be referred in case of need.

Activities:

— Obtain permission to gather information from senior local officials and gain access to knowledgeable members of their organizations

— Use the information being collected about localities and activities associated with HRB and about the locations and types of treatment facilities to develop a large-scale map.

Add to this map throughout the study and use it as a reference for targeting fieldwork activities and for identifying features more generally associated with HRB. Use different symbols to mark places where men seek other men for sex, where female sex workers wait for clients, where treatment facilities for STDs/RTIs are located, and so on.

— Prepare additional maps for particular localities where there is considerable information relevant to SASHI.

Different steps in this stage will be carried out by members of the social science and medical teams.

B1: Obtaining information and approval from officials (use B1 in Appendix 5.1)

This step will be carried out by the supervisor of the social science team.

— Explain the study and its purpose and seek general observations about the local situation

— Seek approval for data collection activities from senior officials (e.g. Municipal Commissioner, Chief of Police, District or Corporation Health Officer) whose cooperation is likely to be required for SASHI. Ask their permission for their subordinates to participate in providing information and assistance to SASHI researchers

— Obtain suggestions and recommendations from these senior officials for key individuals, such as direct subordinates or non-official contacts, who will have more detailed knowledge about places and people relevant to SASHI (such as police inspectors in charge of areas where commercial sex work is known to occur, child health (anganwadi) workers in similar areas, community leaders in localities where vulnerable populations reside or congregate).

B2: Conducting interviews with key informants (use B2 in Appendix 5.1)

— Conduct 10-15 semi-structured interviews (use data collection guide and data recording form B2 in Appendix 5.1) with key individuals identified in step B1 and in subsequent steps (e.g. steps in stage C) about:

— places associated with high risk sexual behaviour and patterns of high risk sexual behaviour within particular localities

— populations engaging in such activities (including prostitutes and their clients, men who have sex with men, others who may or do have multi-partner sex)

— the socio-economic and other characteristics of these populations (main occupational groups, ages, places of origin, community affiliations)

— how to obtain access to some of these individuals and locations - who are the key influential people (e.g. brokers, local leaders) related to these activities

— local agencies and organizations which can provide help and support to the populations identified

— individuals, local agencies and organizations which can provide more information about and access to these populations and places

— individuals, local agencies and organizations which may be useful in or able to implement sexual health interventions

The choice of informants for interviews will depend on the site but should include both local officials and others not in official positions. They may include:

- local health and community workers
- police officers
- locals activists and community leaders
- *panwalas* (working in locations already identified)
- hotel and restaurant *(dhaba)* owners (in locations already identified)
- autorickshaw and taxi drivers
- bar/liquor shop owners and workers (working in locations already identified)
- cinema hall workers
- watchmen
- street vendors
- any other person suggested by previous interviewees and/or likely to give useful information about, or provide introductions to, relevant occupational groups, persons or settings represented in the site. For example, this could include mine foremen or dock foremen (for mine or port workers), or people manning highway check-points (for truck drivers).

When an informant is prepared to provide useful information and/or access, they can also become increasingly useful sources of additional information to return to on subsequent occasions during the study, as rapport and understanding is built up with the researchers.

B3: Mapping sites and locations (use B3 in Appendix 5.1)

This step will be carried out by members of the social science team to:

— conduct selected observations (use data collection guide and data recording form B3 in Appendix 5.1) in all locations that have been identified by officials and interviewees in steps B1 and B2 as probable settings where HRB, or social interactions associated with HRB (e.g. men seeking sex with other men, female sex workers seeking clients, other persons having illicit sexual encounters outside marriage) may be taking place.

— conduct observations in parks, on beaches, at bus and railway stations, in cinema halls, in bars, in hotels, at busy intersections or gathering points and in any other locations that can be identified on the basis of local knowledge as likely to be settings for high risk sexual behaviour or for social interactions connected with this.

Observations should be conducted unobtrusively, at different times of night as well as during the day, for periods of a minimum of 30 minutes in each location. Each site should be observed on at least three separate occasions, noting down:

★ types of person at each locale (ages, sex, social class, mode of dress)

★ nature of interactions between individuals

★ number and frequency of interactions between individuals

★ times of the day/night (specify the actual time)

★ any other notable observations

Where the circumstances are appropriate, these observations can be combined with or followed by key informant interviews (B2), participant observation (C1) or individual interviews with those at high risk (C5).

B4: Mapping facilities for STD treatment (use B4 in Appendix 5.1)

This step will be carried out by members of both medical and social science teams. The medical team will identify all qualified dermato-venereology specialists, together with any other qualified allopaths (MBBS doctors) who provide treatment for sexually transmitted diseases in the area. The social science team will identify all other facilities that specialise in providing treatment for STDs in the area, including both qualified (e.g. trained homeopaths, ayurvedic doctors) and nonqualified (e.g. traditional healers, religious specialists, untrained providers of allopathic medicine) practitioners, using information gathered by the medical team and informants and through observation.

— Locate and document ('map') all kinds of facilities (public and private, traditional, religious and allopathic, qualified and nonqualified) where treatment for STDs/RTIs is given. Sources of information will include:

★ local branch of Indian Medical Association

★ local representative or branch of Ayurvedic and Homeopathic doctors, pharmacists and any other medical-professional associations

★ dermatovenereology specialists and gynaecologists at government clinics

★ information gathered from key informants and informants in various localities.

— In large sites, using the information given by these sources and other informants, locate and document all known facilities (clinics and practitioners) that specialise in the treatment of STDs. These should include both dermato-venereologists and also any others who do not have specialised training or qualifications but are known locally to specialise in providing treatment for STDs (whether allopathic or not). Also, locate and document all medical facilities (regardless of specialisation and qualifications) in those neighbourhoods in which vulnerable populations - and STD cases - are likely to be found, based on the information provided by informants and observations in the previous steps (B1, B2 and B3) about settings for HRB.

— In small sites, locate and document all treatment facilities, regardless of whether they specialise in STD treatment.

— Record (using Data Recording Form B4) the name, qualifications if any, type of medical tradition (e.g. allopathic, homeopathic, traditional or religious healer - in the case of non-qualified 'traditional' or 'religious' practitioners also specify which type, such as *'Hindu ojha', 'siddhi vaidya', 'hakim', 'bhagat'* etc. and in the case of allopathic practitioners also record their area of specialisation, such as dermato-venereologist, cardiac surgeon, gynaecologist), address and where possible, contact details of each treatment facility and practitioner identified.

— Add locations of each documented facility to the site map, using a symbol to denote 'STD treatment facility'. (This will help to identify common characteristics and areas of concentration for field research in other steps of the study.) If possible, use different symbols to indicate different types of practitioners, generalists and specialists.

— Identify a sample of 15 pharmacies/medicine shops (selling predominantly "English Medicines") opportunistically, to include some pharmacies near major hospitals and some located in areas which the ongoing mapping exercise suggests may be a focus for people seeking treatment for STDs (e.g. near red light areas or transport centres). In smaller and in rural sites, map all pharmacies/medicine shops in the entire site. Record the shop name, location, contact details and where appropriate, name and qualification of pharmacist or other treatment provider located there, using Data Recording Form B4.

STAGE C: DATA COLLECTION ON HEALTH AND SEXUAL BEHAVIOUR

Purpose: To collect more detailed information about sexual behaviour and about perceptions and practices relating to reproductive and sexual health from local people and those who are likely to be at particular risk of STD/HIV infection. All steps in this Stage will be carried out by members of the social science team.

Activities:

— Conduct fieldwork (using participant observation) in selected locations, to obtain information from those who are otherwise hard to reach about the contexts and settings in which HRB is practised and characteristics of those involved

— Facilitate mapping exercises and group discussions with women in localities where high risk sexual behaviour is known to occur and with men working in occupations that are known for such behaviour

— Obtain individual case histories of STDs and RTIs

— Interview individuals practising high risk behaviour and members of vulnerable populations

C1: Doing participant observation in hard-to-access populations and places (use C1 in Appendix 5.1)

— Frequent (visit on repeated occasions) settings already identified through mapping activities (in Stage B) as probably associated with high risk sexual behaviour

— Interact informally with people in these settings in order to obtain detailed information about relevant aspects of risky sexual behaviour (e.g. type and frequency, contexts, characteristics of the interactions involved) and to establish or improve access to individuals practising high risk behaviour

— Observe contexts in which high risk behaviour occurs, features of such behaviour and related activities relevant to SASHI

This is a key activity which is essential in all sites where persons are, or may be, involved in illicit or socially marginalised behaviour. In these circumstances it is often better to gather information by using an informal approach, in which the fieldworker does not formally request permission to conduct an interview, but interacts with the informant in an ordinary way using naturalistic conversation and informal observation (known as 'participant observation'). In addition, in some situations it may be necessary to use this approach indirectly to start with, where the researcher 'poses' as a participant to collect information and does not identify him/herself as a researcher. Information set out in this protocol for collection in steps C3, C4 and especially, C5 may need to be gathered at least initially through indirect means as part of this step (C1) instead. Therefore, also refer to the data collection guides for these steps to obtain guidance on relevant possible questions and areas of enquiry. In fact, as much information as possible on all topics contained within SASHI should be collected by participant observation (whether direct or indirect), as an ongoing activity along with other steps.

C2: Conducting community-based group discussions with women (use C2 in Appendix 5.1)

Hold at least 3 group discussions with women in localities already identified as associated with HRB. Invite participants through women's societies (mahila mandals), NGO outreach activities, via key informants or personally during informal visits.

— When this step is the first SASHI data collection activity to take place in a locality, first conduct a 'social mapping' exercise to break the ice, familiarise the group with the researchers and one another and collect useful information about HRB in the area and about treatment providers that can be added to SASHI maps (see stage B). Ask participants to make a map of the local area according to their own idea of it, on which they first put major 'landmarks' (such as temples, community centres, crossroads, notable houses that are familiar to everyone) and then locate the local health providers (all types including both qualified and non-qualified practitioners), sites of HRB (which may include locations of illicit sexual activities and meeting places for couples, MSM and SWs and/or places where SWs and others known to practice HRB reside) and places where alcohol is produced and consumed. The map can be drawn on large sheets of paper with coloured pens, or on the ground using sticks and pebbles.

This may be done as the first stage in a single session as a means to initiate group discussion of the topics to be covered subsequently under this step (see below); or, as an initial familiarisation exercise, after which the group can be reconvened for further discussion on a later occasion. When researchers are already familiar with the community, its characteristics and the geographical area, this social mapping exercise could be omitted.

— Collect information (in group discussions) on:
  - ★ local characteristics of the community and main problems or concerns of women there
  - ★ main health problems identified by women
  - ★ local terms for symptoms and illnesses associated with RTIs (including STDs)
  - ★ awareness about STDs/RTIs/HIV/AIDS
  - ★ perceptions of the causes of RTIs (including STDs), how these infections are recognized (symptoms) and which are associated with sexual transmission
  - ★ treatment-seeking practices for reproductive tract infections (including STDs) and any obstacles to obtaining advice and treatment
  - ★ preventative practices for RTIs and STDs including condom use, behavioural practices and prophylactic medication
  - ★ perceptions of risk relating to sexual and reproductive health
  - ★ patterns of high risk sexual behaviour and perceptions of these
— Identify any women participating in the discussion who may have experienced an RTI/STD or are identified by the researchers or the group as likely to have/have recently had an STD/RTI and arrange with them separately for an individual interview (see C4).

C3: Conducting group discussions with men at high risk - occupational groups (use C3 in Appendix 5.1)

Hold a minimum of 5 group discussions with small groups of men who are likely either to be particularly vulnerable to infection, or to have detailed knowledge of high risk sexual

behaviour and situations in which it occurs in the area. Select occupational groups for inclusion in this step on the basis of information obtained in the previous steps and stages. Vulnerability to infection or familiarity with HRB locally may be due to occupational mobility and disposable income, access to marginalised individuals through that occupation or the neighbourhoods in which they live, or other circumstances on which information has been obtained in previous steps that indicates that high risk sexual behaviour is common among men in that occupational group. (Possible examples are male migrant labourers, transport industry workers such as truck, taxi and rickshaw drivers, men working in businesses or services which involve a lot of travelling and staying away from home, policemen, military personnel, sailors, but this will vary according to characteristics of the site.)

— When this step is the first SASHI project activity to be conducted in a particular locality with co-workers who live or work in that geographical locality, first conduct a 'social mapping' exercise to break the ice, familiarise participants with researchers and the study and to provide other useful information about HRB in the area and about local treatment providers that can be added to SASHI maps (as part of stage B). Ask the group participants to make a map in the same way as described for women in step C2.

Again, this may be done either as the first stage to initiate group discussion of the topics to be covered later (see below) or as an initial familiarisation exercise, with the group reconvened for further discussion on a later occasion. When researchers are already familiar with the participants, the characteristics of that group and the geographical area, this exercise can be omitted. When a group consists of men who work in the same occupation in the study site but are not residents or co-workers of a particular geographical locality within it, this exercise should not be conducted.

— Collect information (in the group discussions) on:

★ awareness about STDs/RTIs/HIV/AIDS

★ patterns of high risk sexual behaviour

★ perceptions of risk relating to sexual and reproductive health

★ perceptions of the causes of STDs/RTIs and how these infections are recognized (symptoms)

★ local terms for symptoms and illnesses associated with STDs/RTIs

★ treatment-seeking practices for STDs/RTIs

★ preventative practices for STDs including condom use and prophylactic medication

★ Identify any individuals who consider themselves to have had an STD or are identified by researchers or the group as likely to have/have recently had an STD,

and arrange with them separately at the end of the discussion to interview them individually (see next step).

C4: Collecting illness case histories — community-based (use C4 in Appendix 5.1)

— Conduct 5-10 semi-structured interviews with individuals who report or are identified as having recently had a health problem characteristic of a RTI or STD, collecting details on:

★ awareness and perceptions of symptoms relating to STDs/RTIs
★ full treatment history, including self-treatment
★ sources of information about these infections
★ influences on decision-making about treatment
★ individual sexual history

C5: Interviewing individuals practising high risk sexual behaviour and members of vulnerable populations (use C5 (i), (ii) or (iii) in Appendix 5.1)

— Interview individuals known or likely to practise high risk sexual behaviour. These will include (where identified through previous steps): female sex workers (use data collection guide and data recording form C5(i)); men who have sex with men (use data collection guide and data recording form C5(ii)); and where possible, clients of sex workers, other partners of sex workers including brokers (pimps) and boyfriends, as well as other individuals - regardless of occupation or social position - who acknowledge having non/extra-marital sexual partners or sexual health problems like STDs (use data collection guide and data recording form C5(iii) for all of these).

— Interview members of populations already identified as being particularly vulnerable to STDs/RTIs in the previous steps (such as, depending on the site, single male migrant industrial workers, rag pickers, street-based persons, *hijras/alis)* (use data collection guide and data recording form C5(iii)).

STAGE D: STUDY OF STD/RTI SERVICES

Purpose: To collect information about what kinds of treatment people with STDs get, their experiences with treatment-seeking and the quality of the treatment provided.

Activities:

— Arrange for surrogate (also known as 'dummy' or 'mystery') patients to visit practitioners who give treatment for STDs and if appropriate, pharmacies/medicine shops

— Collect information on service provision for STD treatment by interviewing pharmacists and medical practitioners

— Estimate numbers of patients seeking treatment in the private sector by enrolling STD treatment providers in data collection

— Gather information on treatment-seeking behaviour, service quality and patient satisfaction through exit interviews with STD patients

Different steps in this stage will be carried out by members of both the social science and the medical teams.

D1: Making surrogate client visits (use D1 in Appendix 5.1)

This step is arranged and implemented by the social science supervisor alone, without informing or involving the rest of the research team. This is essential to protect the identities of practitioners contacted and to maintain confidentiality so that accurate information about actual patient-provider interactions and treatment-giving behaviour can be obtained. Carry out this step in the early stages of SASHI, before interviews with treatment providers (step D3) and collection of patient data by treatment providers (step D4) have begun.

— Recruit and brief a suitable male aged between 25 and 40 years of age to carry out visits to STD treatment providers in the guise of a surrogate or 'dummy' (pretend) patient.

— With the surrogate client, who should be willing and able to act convincingly as an STD patient, construct a suitable family background, name and occupation and combine this with the surrogate client history given in data collection guide D1 of Appendix 5.1.

— Direct and monitor the surrogate in carrying out visits to ten practitioners who specialise in treating STDs (whether qualified or not), including a minimum of three who are qualified allopathic specialists in dermato-venereology and a selection from different medical systems represented among local practitioners (such as ayurvedic, homeopathic and unani).

— Maintain a confidential list of all practitioners who are visited.

— Ensure the data are either recorded by the surrogate client immediately after the clinic visit or, preferably, hold a debriefing session immediately afterwards, at which the supervisor records exact details of the consultation as described by the surrogate client (in either case, use data recording form D1 of Appendix 5.1).

— Make sure that all health providers visited are subsequently interviewed by a field researcher as part of step D3.

— Make sure all prescriptions collected are given the same code number as the data recording form for that visit. If necessary, once all visits are completed, show all collected prescription slips to a pharmacist for deciphering any medicines prescribed.

— Add full details of all medicines which were prescribed to the data recording form for the relevant visit and file the original prescription together with the appropriate form.

D2: Conducting interviews and observations at pharmacies/medicine shops (use D2 (i) and (ii) in Appendix 5.1)

This step is carried out by social science researchers. Care must be taken by the researchers when introducing themselves and the research topic to make sure that they are not identified with any regulatory agencies (such as Government health or other inspectors, drug controllers etc.). If possible also interview drug representatives working for pharmaceutical companies who visit these pharmacies, as they can also give useful information regarding the pharmacy trade, sales, and specialist STD practitioners in the area. Record all information (from both interviews and observations) on data recording form D2 in Appendix 5.1.

— Interview the staff serving in about 15 pharmacies/medicine shops selling mainly allopathic ('English') medicines, selecting several pharmacies near major hospitals and the rest from shops located in areas which may be a focus for people seeking treatment for STDs (e.g. near State transport facilities, in red light areas, near specialist STD clinics). Collect information (use data collection guide D2(i)) on:

  ★ populations served and their characteristics (age, gender, social class, place of origin etc.)

  ★ whether pharmacy worker can identify patients seeking medication for STDs

  ★ whether people ask for advice about how to treat particular problems/symptoms

  ★ estimated number of people seeking treatment and drugs for STDs and their characteristics

  ★ estimated number of condoms sold and who buys them

  ★ self-medication practices with antibiotics for STDs

— Before, during and after these interviews, observe transactions in these pharmacies (use data collection guide D2(ii)), noting instances and frequency of :

  ★ advice-seeking from pharmacists on the basis of symptoms described by customers

  ★ requests for antibiotics without presentation of a prescription and provision of medicines in response to these requests

  ★ occurrence of treatment-seeking specifically for symptoms associated with RTIs or STDs

  ★ condom purchases and characteristics of purchasers

D3: Conducting interviews with practitioners (use D3 of Appendix 5.1)

Interviews of allopathic practitioners will be carried out ideally by pairs of researchers consisting of either one medical and one social science researcher, or two social science researchers if one is medically trained. Interviews with non-allopathic practitioners can be carried out either by these same pairs or exclusively by social science researchers.

— Interview all practitioners in the site who are known to specialise in providing treatment for STDs (including dermato-venereologists and other allopathic practitioners who see many STD patients, practitioners of traditional medicine, unqualified practitioners and Registered Medical Practitioners (RMPs)). Also interview all general (family) practitioners who work in localities which have a relatively high proportion of vulnerable populations (as identified in earlier steps of the situational analysis), whether or not they specialise in STD treatment. In all interviews gather information on:

  ★ qualifications and length of time in their type of practice

  ★ experience (length of time practising) in the geographical area

  ★ population served and their socio-demographic characteristics

  ★ frequency and types of STDs seen

  ★ nature of treatment provided and advice given

  ★ their patients' knowledge of and attitudes to STDs

  ★ patients' treatment-seeking histories, including self-medication

  ★ practitioner's explanation of STD prevalence in the area

  ★ practitioner's knowledge and views on high risk sexual behaviour in the area

— Request permission from selected practitioners who confirm that they see more than 3 STD patients per week, to interview their STD patients (see step D5).

— Request those practitioners who confirm that they see more than 1 STD patient per week, to collect data on their STD patients over a specified period, as explained in the next step (D4), and provide them with relevant forms, showing them that only minimal and straightforward information is being requested.

D4: Arranging collection of patients data by practitioners providing STD treatment (use D4 of Appendix 5.1)

This step is to be carried out by both teams, with a medical researcher arranging data collection from dermatovenereologists and any other allopathic treatment providers

specialising in STD treatment provision, and a social science researcher arranging data collection from other treatment providers. Do not commence this data collection step and the discussions required for arranging it with the practitioners until after the surrogate client visits (step D1) have been completed.

— After getting their agreement to participate in this step during the interviews conducted in step D3, request practitioners who regularly see STD patients to collect data on all new STD patients seen over a pre-specified six week period on a structured data recording form (provide each participating practitioner with Form D4 of Appendix 5.1). Participants will include doctors in government dermatovenereology clinics and doctors seeing patients in charity (trust) hospitals, private hospitals and in their own clinics, as well as other practitioners. When going through the form which will be completed, emphasise that only the first consultation by a patient for a particular STD episode should be recorded. Inform them of the start date for data recording and ask them not to begin data collection until this time.

— On the day before the start of the specified six-week recording period, telephone or visit each participating treatment provider and remind them of the need to start this activity on the following day. After one week, telephone or visit each participating treatment provider and check that data collection is proceeding; if not, identify the reasons and, if possible, correct these.

— Contact each participating provider again at least one week before the end of the specified recording period, to remind them of the need to continue collecting data until the specified end date.

— After completion of the recording period, collect the completed forms from each provider and provide details of planned feedback of the overall results in due course.

D5: Doing exit interviews with STD patients (use D5(i), (ii) or (iii) of Appendix 5.1)

Members of both the research teams will participate in this step. The medical supervisor should get permission from a selection of both public and private allopathic STD treatment providers (identified in earlier steps) for a member of the team to interview their STD patients. For practical reasons, those practitioners in the site who see the largest numbers of STD patients should be enlisted for this step. Interviews should ideally be conducted with the patient alone, not in the presence of the practitioner (but see below for possible modifications if this is not permitted). Medically qualified members of either the social science or the medical team should conduct the interviews with patients, following appropriate training (in the training period) and subsequent guidance from the social science supervisor. Each interview should be done by one researcher, not in pairs and all information from exit interviews should be recorded on data recording form D5.

— Interview a sample of at least 30 STD patients after their consultation with the practitioner. Request each participating practitioner to 'refer' the patient to the researcher at the end of the consultation. Wherever possible, ask the treatment provider to provide a place within their facility for interviewing patients privately. Otherwise approach the patient directly for a brief interview as they leave the treatment facility, if they have been identified as an STD patient by the practitioner. At least 10 patients seeking treatment from a public provider and 10 patients from at least two different private providers should be interviewed, on:

  ★ their experiences of obtaining treatment for STDs

  ★ their account of treatment received and advice given

  ★ levels of satisfaction with the service provided

  ★ complete history of prior treatment-seeking for this problem (and, if relevant, for similar previous episodes)

  ★ details of high risk sexual behaviour and history of sexual contacts

  ★ their knowledge regarding STDs/RTIs/HIV/AIDS

  ★ accounts of STD cases among relatives, friends and acquaintances

Use data collection guide D5(i) for all patients seeing treatment providers who are not participating in clinical investigations for SASHI (i.e. in ordinary circumstances). However, use data collection guide D5(ii) for all patients seeing treatment providers who are also participating in clinical investigations for SASHI as part of stage E, because these investigations are not usual procedure and so need to be excluded from the topics discussed in the interview. If practitioners refuse to allow a researcher to interview patients but offer to conduct these interviews themselves during the consultation, provide the practitioners with the specially adapted version of data collection guide D5(iii) for this purpose, together with the data recording forms for D5. Practitioners conducting their own interviews should be advised that the interview may be easier to conduct before, rather than after, the clinical consultation, once the initial presenting problem (indicating a possible STD) has been established. (In this type of interview, patients evaluation of consultation is excluded, so it is not necessary that the interview be conducted only after the consultation is complete). However, serious efforts should be made to ensure that some exit interviews are conducted directly by researchers independently of the practitioners, since patient satisfaction cannot otherwise be assessed and the quality of interviews carried out by untrained practitioners may be very variable.[1] If the practitioner wishes to be present during the exit interview, this should be recorded on the data recording form for the interview.

D6: (additional step): Surrogate client visits to pharmacies/medicine shops (use D6 in Appendix 5.1)

This step will be carried out by the social science supervisor in collaboration with the medical supervisor. If data from exit interviews with STD patients (step D5), from illness case histories (step C4) and/or from interviews with health providers, including pharmacists (D2 and D3), suggest that many or most patients are purchasing medication over the counter to self-treat RTIs and STDs, then carry out this step (D6) in addition to the other steps in this stage.

— Recruit a suitable male aged 25-40 years as for step D1 and train him to follow a script simulating a customer wishing to purchase medication at a medicine shop or pharmacy without prescription.

— An exact script must be developed based on local information collected in the previous steps about how these approaches are made and should imitate these appropriately. For instance, if medical practitioners have suggested that their STD patients are familiar with the names of particular antibiotics and often initially treat themselves by purchasing them directly from shops, the script should include an attempt by the surrogate client to purchase one of these named drugs in a similar manner. If interviews with pharmacists or case histories suggest that STD patients tend to approach medicine shops for advice and medication by describing symptoms, the surrogate patient should present himself as having an appropriate symptom for which he is seeking treatment. The medical supervisor should design the scenario in order to ensure medically accurate presentation of symptoms or requests for medication. Data recording and other aspects of this step should be conducted according to the guidelines given on data recording form D6.

STAGE E: CLINICAL AND EPIDEMIOLOGICAL STUDIES ON REPRODUCTIVE TRACT INFECTIONS / STDs

Purpose: To gather information on (i) the prevalence of aetiologic agents in patients presenting with symptoms of RTIs/STDs, (ii) the level and the pattern of antibiotic resistance of Neisseria gonorrhoea, (iii) the treatment seeking behaviour and condom use among RTIs/STD patients and (iv) the prevalence of important symptomatic and asymptomatic RTIs/STDs in the general adult population.

Activities:

— Male STD study **(step E1):** Study STD aetiologies in at least 50 men presenting with STD symptoms at public and private dermatovenereology (STD) clinics

— Additional urethritis study **(step E2):** Collect additional urethral specimens from male STD patients presenting at public and/or private dermatovenereology (STD) clinics and determine the antibiotic sensitivity of Neisseria gonorrhoea in up to 100 strains

— Female RTI study **(step E3):** Study RTI/STD aetiologies in at least 50 women presenting

symptoms of genital infections at public and private gynaecologic and dermatovenereology (STD) clinics

— ANC study **(step E4):** Study STD/RTI aetiologies in 100 ANC clinic attenders from public ANC clinics, as a surrogate for the general female population

— Additional ANC study (**step E5):** Study the prevalence of gonococcal and chlamydial infections in an additional 400 ANC attenders from public ANC clinics

— Male general population study **(step E6):** Study STD/RTI aetiologies in 500 men from the general male population.

All steps in this stage are carried out by the medical team. Every step in this stage contains the following sequence of essential components:

— **Determine the sample frame :** decide on the number required and the method of selecting a sample.

— **Determine eligibility :** define inclusion criteria and check that they are met by each study participant.

— **Obtain consent :** inform each eligible person about the aims of the study, obtain consent, and document this through signature or left thumb impression from each participant on the respective data collection form.

— **Assign study number :** provide a unique identification number to each participant.

— **Collect data :** administer the questionnaire designed for the respective study, strictly adhering to the standardised study protocol described for each step and demonstrated during the training period.

— **Collect, transport and store the specimens :** strictly according to the protocol as described below and demonstrated during the training period.

— **Process specimens :** label all samples immediately at the bedside, using the unique identification number (the same number used on the questionnaire). For ulcer specimens add the suffix 'UL' to the end of each identification number in order to distinguish them from urethral samples. Label cryovials before taking samples, using permanent ink on sticky labels which are known to be able to withstand moisture during freezing. Label slides using a diamond pen. Transfer samples within 30 minutes of collection to the laboratory for further processing.

— **Perform laboratory tests :** on collected specimens as per the standard procedures or guidelines provided along with the test kit. General guidelines are given in appendix 4a.

— **Treat patients :** feed laboratory data back to the clinic at which study participants are attending, except in the case of the additional ANC study (step E5) and the male general population study (step E6) which are conducted in an unlinked anonymous way. Send

the slips from the bottom of the consent form to the relevant clinics; this links the study number to the patient's name and allows identification of laboratory results with a particular patient, and the incorporation of these findings into patient management. Ensure patient management is carried out according to the routine procedures prevailing at the study site, including partner notification and treatment.

— **Conduct quality control :** check quality of data and specimen collection, and of laboratory tests. Each questionnaire should be checked by the medical supervisor at the end of each day in the presence of the clinician who collected the data. Questionnaires should be checked for omissions and inconsistencies. Laboratory quality control procedures are detailed in appendix 5.22.

— **Record data :** enter data regularly into a microcomputer.

— **Monitor work progress and rectify implementation problems :** the medical supervisor and the clinicians meet daily to discuss and rectify any logistical problems (e.g. concerning the preparation of sample collection kits, availability of blank questionnaires, facilities for examination). Each week the entire team (including data entry/analysis and laboratory personnel) meets to review progress and discuss problems. The data entry operator provides feedback on the quality of completed questionnaires and laboratory data sheets.

— **Analyse data :** analyse data as soon as possible after the end of the data collection period and document the results.

— **Write study report :** prepare a detailed report on methods used, difficulties encountered and results obtained. Start preparation of report during the data collection period. Prepare the final report after completion of data collection period.

As discussed in Chapter 2, SASHI will be implemented in different sites which may have different levels of laboratory facilities. Available financial resources may also vary. For implementation of the studies listed above, one of the three options - minimal, standard and comprehensive - can be selected depending on the level of laboratory technology available and the extent of data required. Some studies can only be carried out if advanced facilities are available, but not all of the studies described for the comprehensive option need to be conducted at every site where SASHI is implemented within a region. The three options are described in detail in Table E1 and are referred to in the text of the following steps of this protocol. The Project Coordinator and medical supervisor, together with any other agencies responsible for implementing SASHI and with advisory input from the SASHI Resource Group, should decide which studies can and should be conducted at the site and select the appropriate option accordingly. In addition to the laboratory facilities available (basic, intermediate or advanced, as described in Table E1) and the types, detail and accuracy of data that need to be collected for planning purposes, availability of skilled personnel for doing each type of laboratory test at the designated laboratory or laboratories where SASHI tests will be conducted (this may be at the site and/or at a collaborating laboratory) should also be taken into consideration while deciding which studies should be conducted. Steps, described below, relate to the comprehensive option and the number of specimens taken will be reduced if the standard or minimal options are carried out.

Table E1: Medical Studies on STDs/RTIs (stage E): Overview of Options

	Option 1 - Minimal Provides some essential Information for intervention programme planning. Minimum programme for all SASHI sites.	**Option 2 - Standard** Provides most of the information needed for intervention programme planning. Only limited information on magnitude of STD problem in the general population. Recommended to be performed at all sites, if feasible.	**Option 3 - Comprehensive** Provides more detailed information for intervention programme planning. Recommended to be performed at one site in each State or region.
Level of technology	Basic	Intermediate	Advanced
Equipment required	Microscope, refrigerator, VDRL shaker centrifuge	Refrigerator, shaker, incubator, centrifuge, ELISA reader, ELISA washing system	As for option 2, plus laminar flow, deep freezer, microcentrifuge, thermal cycler, gel apparatus, photography equipment, PCR equipment
Tests required	Gram stain, wet preparation; RPR (or VDRL)	As for option 1, plus TPHA, HIV ELISA; CT (EIA), CT blocking assay, NG culture facility, Phadebact test, Oxidase and Beta-Lactamase test, E-test; InPouch for TV infection	As for option 2, plus PCR for NG, CT.
E1: Male STD study (at least 50 male STD patients)	Urethral smear: NG, NSU. Urethral wet prep: TV Serum: syphilis (RPR)	Urethral smear: NG, NSU, CT (EIA); NG culture and sensitivity. Urethral wet prep: TV. Serum: syphilis (RPR,TPHA); HIV. Ulcers: donovanosis (Giemsa), HSV-2 (EIA), LGV (CT EIA).	Urethral smear: NG, NSU; NG culture and sensitivity. TV (culture). Serum: syphilis (RPR, TPHA); HIV; PCR for NG and CT on urine samples. Ulcers: donovanosis (Giemsa), LGV (CT EIA).
E2: Additional urethritis study (target: 100 NG strains).	—	Urethral smear: NG, NSU, CT (EIA); NG culture and sensitivity. Urethral wet prep: TV.	As for option 2, plus PCR for NG and CT on urine samples.

	Option 1 - Minimal	Option 2 - Standard	Option 3 - Comprehensive
E3: Female RTI study (at least 50 women with vaginal discharge or other RTI-related complaints)	Cervical smear: NG. Vaginal smear: BV, CA. Vaginal wet prep: TV, CA Serum: syphilis.	Cervical smear: NG, CT (EIA); NG culture and sensitivity. Vaginal smear: BV, CA. Vagina l wet prep: TV, CA, pH. Serum: syphilis (RPR,TPHA); HIV. Ulcers: LGV (Giemsa), HSV-2 (EIA).	Cervical and vaginal smears: as for option 2. Vaginal fluid: TV culture. Serum: as for option 2. Urine: PCR for NG and CT. Ulcers: donovanosis (Giemsa), LGV (CT EIA).
E4: ANC study (100 ANC attenders)	As for female RTI study	As for female RTI study (see above), but without NG culture and sensitivity testing	As for female RTI study (see above), but without NG culture and sensitivity.
E5: Additional ANC study (400 ANC attenders)	—	—	Urine: PCR for NG and CT.
E6: Male general population study (500 men)	—	—	Urine: PCR for NG and CT.

Key: NG - Neisseria gonorrhoeae, CT - Chlamydia trachomatis, TV - Trichomonas vaginalis, CA - Candida albicans, NSU - non-specific urethritis, BV - bacterial vaginosis, TP - Treponema pallidum, LGV - lymphogranuloma venereum, HSV-2 - Herpes simplex virus type-2, HD - Haemophilus ducreyi, RPR - Rapid plasma reagin test, VDRL - Venereal disease research laboratory test, TPHA - Treponema pallidum haemagglutination assay, EIA - Enzyme immuno assay, PCR - Polymerase chain reaction test

E1: Male STD study

Sample frame: Recruit consecutive patients from the major government STD clinic for questionnaire completion and clinical data collection. All possible efforts should be made to recruit an opportunistic sample of patients from private dermatovenereologists a total fo 50 patients from all sources should be recusited for a field set of invwstigations[2].

Eligibility criteria: Restrict eligibility to male patients whose primary presentation relates to symptoms or signs of STDs/RTIs.

Obtaining consent, assigning study number and collecting data: Use data collection guide E1 in Appendix 5.1 to document informed consent and the questionnaire in data

recording form E1 in Appendix 5.1 to administer questions and to record findings from the clinical examination described below. The form may be modified during the training period to take local variations and interests into account.

Perform a clinical examination which includes :

— examination of the genitalia for urethral discharge, ulcer and growth

— examination for inguinal lymph node swelling

— examination of the anus for fissure, growth or discharge

After examination, record presumptive clinical diagnosis on the data recording form E1/ E2/E3 (Appendix 5.1), and describe how this diagnosis was arrived at.

The kit required for collection of specimens is prepared in the laboratory according to checklist E1 (Appendix 5.3), and transported to the clinic each morning. Collect specimens from all male STD cases as follows:

— **Urethral swab 1 :** after milking the deeper part of the urethra from the perineal part upwards, insert a wooden-shafted swab into the proximal urethra and prepare a smear specimen by rolling the swab onto a glass slide for the diagnosis of Neisseria gonorrhoea by gram staining and microscopy (options 1-3, see table E1).

— **Urethral swab 2 :** take a second wooden-shafted swab as above and plate it at the bedside onto a selective medium for culturing Neisseria gonorrhoea. Put the plate into a candle jar immediately and create a carbon dioxide (CO_2) atmosphere in the jar by lighting the candle. Also maintain a humid atmosphere within the jar by keeping a moist ball of cotton at the bottom of the jar. Transport specimens to the incubator as soon as possible (options 2-3).

— **Urethral swab 3 :** insert a dacron-shafted swab which should be passed deeper (about 3 cm) into the urethra and rotate it slowly. Then insert the tip of the swab into a cryovial containing chlamydia transport media, and break it off, so that the tip is immersed in the fluid (options 2-3).

— **Urethral swab 4 (optional) :** collect urethral fluid either directly onto a glass slide or with the help of a wooden-shafted swab, add a drop of saline and request the microbiologist to examine this wet preparation soon afterwards microscopically for Trichomonas vaginalis (option 1 and 2). In sites where advanced laboratory facilities are available (so that option 3 - Comprehensive - can be implemented), inoculate the specimen for culture of Trichomonas vaginalis using the InPouch kit.

Collect additional specimens from patients with ulcers and /or perforated buboes from the entire floor area of the ulcer or perforated bubo (options 2 and 3 only):

— **ulcer/bubo specimen 1 :** wooden-shafted swab, rolled on glass slide for microscopy for the diagnosis of donovanosis using Giemsa or Leishman stain.

— **ulcer/bubo specimen 2 :** dacron-shafted swab, end of swab broken into a cryovial containing chlamydia transport media for the diagnosis of lymphogranuloma venereum LGV by CT EIA

— **ulcer/bubo swab 3 :** wooden-shafted swab, end of swab broken into a cryovial containing herpes transport media, for the diagnosis of Herpes simplex virus-2 by HSV-2 EIA (option 2, see table E1).

Note that if there is an ulcer and a perforated bubo, the researchers have to collect a total of 7 specimens (as described above).

— Draw a venous blood sample for syphilis serology (option 1-3) and for HIV serology (option 2-3). HIV testing as part of SASHI should only be carried out if agreed with the relevant State Government authority (usually, the State AIDS Cell or Society). HIV testing may either be anonymous unlinked testing (in which case the results should not be linked back to the patient) or patient-based testing, in which case consent should be obtained for HIV testing and HIV counselling should be made available. Any HIV testing as part of SASHI needs to be integrated with existing local practice regarding HIV testing at dermatovenereology clinics.

— Obtain urine sample from each patient after swabs are collected for the diagnosis of Neisseria gonorrhoeae and Chlamydia trachomatis by PCR (option 3 only, see table E1). Instruct the patient to provide the very first portion of urine only. The patient should not have urinated for at least 1 hour before this sample is taken. If a patient reports urination during this period, ask him to wait until the required time gap is met.

E2: Additional urethritis study

After the main Male STD Study (step E1) is completed, in sites where options 2 or 3 are being conducted (see table E1), continue to recruit patients presenting with suspected STDs (urethral discharge or burning sensation during micturition). Take urethral specimens only, following the same procedures as in the main study. The target will be to obtain as many strains of Neisseria gonorrhoeae as possible for antibiotic sensitivity investigation. Use data recording form E1/E2/E3 in Appendix 5.1 for this purpose and record consent using data collection guide E1/E2/E3 (Appendix 5.1).

E3: Female RTI study

Sample frame : Recruit patients from the major government gynaecology clinic and simultaneously from the major government STD clinic for questionnaire completion and clinical data collection[3]. At the gynaecological clinic, recruit patients using a random selection process; for example, by throwing a dice each time an eligible patient enters the clinic

room, and by selecting all women for whom the dice shows a six. Choose a sampling scheme which results in a suitable number of patients being sampled each day (this will depend on the total number of patients presenting and on the number of medical researchers - a balance must be achieved between sampling enough patients daily for the total sample needed for SASHI to be recruited within the overall time frame of the study, and recruiting too many each day for the researchers to manage during clinic hours).[4] The process of random selection ensures that sample bias is avoided. At the STD clinic, recruit all presenting female STD patients. An additional opportunistic sample of 20 patients may be recruited from private gynaecologists or dermatovenereologists, in a similar way to that described for the male STD study.

Eligibility criteria : Restrict eligibility to female patients aged 15 to 45 whose primary presentation relates to symptoms or signs of STDs / RTIs (including vaginal discharge).

Obtaining consent, assigning study number and collecting data : Use data collection guide E3 in Appendix 5.1 to document informed consent and the questionnaire that is provided as data recording form E3 (Appendix 5.1) to ask and record answers to verbal questions and to record findings from the clinical examination described below. The form may be modified during the training period to take local variations and interests into account.

Perform clinical examination which includes :

— examination of the genitalia for vaginal discharge, ulcer and growth

— examination for inguinal lymph node swelling

— examination of the anus for fissure, growth or discharge

— bimanual palpation for fornix tenderness, mass and cervical tenderness

— speculum examination of the cervix for ectopy, inflammation, discharge, ulcer and growth

After examination, record presumptive clinical diagnosis on the form E1/E2/E3 and describe how this diagnosis was arrived at.

The kit required for collection of specimens is prepared in the laboratory according to checklist E3 (Appendix 5.3) and transported to the clinic each morning.

Introduce a bivalve speculum, clean the cervix with a dry cotton swab (without antiseptics) and collect specimens as follows:

— **vaginal swab 1 :** collect vaginal fluid from the vaginal walls and from the posterior fornix using a wooden-shafted swab. Roll this swab on a glass slide for the diagnosis of bacterial vaginosis and candidiasis by gram staining and microscopy. Then apply the same swab to pH paper and record the pH value (options 1-3, see table E1).

— **vaginal swab 2 :** collect vaginal fluid from the vaginal walls and from the posterior fornix using a wooden-shafted swab and apply the specimen on a glass slide. Add a drop of saline and request the microbiologist to examine this wet preparation soon afterwards microscopically for Trichomonas vaginalis (options 1 and 2)[5]. In sites where the laboratory tests specified for option 3 are being carried out, inoculate the specimen for culture of Trichomonas vaginalis using the InPouch kit.

— **cervical swab 1 :** insert a wooden-shafted swab into the cervical os for about 1 cm, rotate it slowly and prepare a smear specimen by rolling the swab onto a glass slide for the diagnosis of Neisseria gonorrhoea by gram staining and microscopy (options 1-3, see table E1).

— **cervical swab 2 :** take another wooden-shafted swab as above and plate it at the bedside onto a selective medium for culturing Neisseria gonorrhoea. Put the plate into a candle jar immediately and create a CO_2 atmosphere in the jar by lighting the candle. Also maintain a humid atmosphere within the jar by keeping a moist ball of cotton at the bottom of the jar. Transport specimens to the incubator as soon as possible (options 2-3).

— **cervical swab 3 :** insert a dacron-shafted swab into the cervical os for 1-2 cm and rotate it slowly. Then insert the tip of the swab into a cryovial containing chlamydia transport media, and break it off, so that the tip is immersed in the fluid (options 2-3).

Collect additional specimens from patients with ulcers and/or perforated buboes from the entire floor area of the ulcer or perforated bubo (options 2 and 3 only):

— **ulcer/bubo specimen 1 :** wooden-shafted swab, roll on glass slide for microscopy for the diagnosis of donovanosis using Giemsa or Leishman stain.

— **ulcer/bubo specimen 2 :** dacron-shafted swab, break end of swab into a cryovial containing chlamydia transport media for the diagnosis of lymphogranuloma venereum LGV by CT EIA

— **ulcer/bubo swab 3 :** wooden-shafted swab, break end of swab into a cryovial containing herpes transport media, for the diagnosis of Herpes simplex virus-2 by HSV-2 EIA (option 2 only, see table E1).

Note that if there is an ulcer and a perforated bubo, medical researchers must collect a total of 7 specimens (as specified above).

— Draw a venous blood sample for syphilis serology (options 1-3) and for HIV serology (options 2-3). HIV testing as part of SASHI should only be carried out if agreed with the State Government authority (usually the State AIDS Society or Cell), so that it could be incorporated in the ongoing State sentinel surveillance activities. HIV testing may either be anonymous unlinked testing (in which case the results should not be

linked back to the patient) or patient-based testing, in which case consent should be obtained for HIV testing and HIV counselling should be made available. Any HIV testing as part of SASHI needs to be integrated with existing local practice regarding HIV testing at dermatovenereology clinics.

— Obtain a urine sample from each patient after swabs are collected for the diagnosis of Neisseria gonorrhoeae and Chlamydia trachomatis by PCR (option 3 only, see table E1). Instruct the patient to provide the very first portion of urine only. The patient should not have urinated for at least 1 hour before this sample is taken. If a patient reports urination during this period, ask her to wait until the required time gap is met.

E4: ANC study

Sample frame : Recruit 100 pregnant women from the major government ANC outpatient clinic in the site. If the clinic is very busy, recruit patients using a random selection process similar to the one described for the Female RTI Study; for example, the nurse who performs the height and weight examinations on all women can throw a dice for each woman meeting the eligibility criteria who enters the examination room.

Eligibility criteria : Restrict eligibility to women whose primary reason for attendance is routine antenatal care. These women may or may not report RTI related symptoms in addition.

Obtaining consent, assigning study number and collecting data : Use data collection guide E4 (Appendix 5.1) to document informed consent and data recording form E4 (Appendix 5.1) to administer questions and to record findings from the clinical examination described below. The form may be modified during training period to take local variations and interests into account.

Perform clinical examination which includes :

— examination of the genitalia for vaginal discharge, ulcer and growth

— examination for inguinal lymph node swelling

— examination of the anus for fissure, growth or discharge

— speculum examination of the cervix for ectopy, inflammation, discharge, ulcer and growth.

After examination, record presumptive clinical diagnosis on the form E4 and describe how this diagnosis was arrived at.

The kit required for collection of specimens is prepared in the laboratory according to checklist E3 (Appendix 5.3) and transported to the clinic each morning.

Follow the same specimen collection procedure as described in the protocol for the Female RTI Study (see E3 above), but without NG culture and sensitivity.

E5: Additional ANC study

Sample frame : After the main ANC Study (step E4 above) is completed, in sites allowing laboratory work according to option 3 (see table E1), continue to recruit another 400 pregnant women. Change the random sampling frame to recruit more women per day, since recruitment will take much less time as only limited investigations are performed.

Eligibility criteria : As for the main ANC study, restrict eligibility to women whose primary reason for attendance is routine antenatal care. These women may or may not report RTI-related symptoms in addition.

Obtaining consent, assigning study number and collecting data : Use data collection guide E5 (Appendix 5.1) to document informed consent, and data recording form E5 (Appendix 5.1) to administer and record responses to the questionnaire. The form may be modified during the training period to take local variations and interests into account. A clinical examination is not required for the purpose of the study. It is vital that the questionnaire is administered in exactly the same way as it is for the first 100 women.

Take urine specimens only, following the same procedures as in the main study.

E6: Male general population study

Sample frame and eligibility criteria : This study can be performed only in sites with access to advanced laboratory facilities and will only be carried out when SASHI option 3 (see table E1) has been selected. Recruitment of a male general population sample will depend on which groups may be readily accessible in a given city or other geographical area. These could be, for example, factory workers, workers in a large government or local administrative office (municipal council, railway services) or the workforce of a large hospital. It is important that the source population for this sample should cover the full socio-economic spectrum.

Select a random sample of around 550 men from the workplace in question, aiming at obtaining urine specimens from 500 men (allowing for refusals to participate). The exact sampling strategy will depend on local contingencies[6]. If there are several shifts in a workplace it is important to recruit a random sample from each shift. If there are 600 or less workers in the site, then no sampling is necessary and the aim should be to recruit all workers.

Obtaining consent, assigning study number and collecting data : In this study urine samples are tested by PCR for chlamydial and gonococcal infection in an unlinked and anonymous manner. Discuss this approach with the State Government authority responsible

for HIV (State AIDS Cell or Society) before commencing the study and obtain approval at this level as well as from the director of the workplace. It is advisable to combine the sample collection with urine examination for glucose and protein, provided consent can also be obtained, and to make the results of these additional tests available as a service to the study participants on the spot. Use data collection guide E6 (Appendix 5.1) to document informed consent and data recording form E6 (Appendix 5.1) to administer and record answers to the questionnaire. The form may be modified during the training period to take local variations and interests into account. No clinical examination will be performed.

Obtain urine sample from each patient. The study participant should not have urinated for at least 1 hour before the sample is taken. If he reports having passed urine during this period ask him to wait until the required time gap is met.

Prepare two aliquots of urine by pipetting them into cryovials. Thereafter perform a dipstick test for glucose and protein on the remaining urine in the original collection container, and feed the results back to the participant immediately.

Store the cryovials with urine in plastic 9x9 containers within a cool box. Transfer the boxes with the specimens into a minus 20 degree freezer as soon as possible.

1 In one of the SASHI pilot studies for example, a private dermato-venereologist refused to allow a researcher to carry out exit interviews but desired to conduct such interviews himself. An appropriately modified data collection guide - provided in Appendix 5.1 as D5(iii) - was therefore prepared. However, practitioners usually have limited familiarity with conducting interviews designed to elicit the patient's views and with recording verbatim responses accurately, so that the data obtained often has limited value. It is therefore important that this approach is avoided, if possible and that consent is obtained instead for a member of the SASHI research team to carry out this step. In another case, the practitioner agreed to this latter approach but insisted on being present for the exit interviews. The data obtained in this case was still of reasonable quality.

2 At least 50 patients with a full set of investigations should be recuicited from the government and private clinics. If it is not possible to obtain full investigations in private clinics then a limited set of investigations can be carried out of an additional sample of private patientss. Sampling strategy will depend upon the willingness of private dermatovenereologists and patients to take part in the study. In SASHI pilot studies, this was achieved in two ways. In one site a trained researcher was stationed at a major private dermatovenereologist's clinic for agreed periods during which STD patients were likely to attend (this may be evening clinics, for example, in which case necessary access to facilities for sample storage and incubators must be arranged beforehand if public facilities are being used, as Government hospital or medical college departments will normally be closed at this time). In this approach the questionnaire and examination data will be the same as for the government clinic study. It may be necessary to reduce the number of laboratory investigations, although the degree to which this is the case will depend upon local circumstances. The minimum set of investigations (as detailed in the main protocol of the Male STD Study) would be urethral swab 1, venous blood and urine collection. However if conditions permit additional investigations can be included. If practical conditions (for example, space) do not permit investigations in the private clinic but the practitioner is willing to refer patients for examination in the government clinic, special arrangements should be made for separately receiving and recording data on these patients in the government clinic and for prompt reporting of the laboratory test results back to the treating practitioner. This approach was taken in the second SASHI pilot site.

3 During SASHI pilot surveys, it became obvious that 50 female patients could not be recruited from government STD clinics alone during the limited time-frame of the SASHI study. Most women with RTIs present themselves at gynaecology clinics, but women with genital ulcers often present at or are referred to STD clinics. Therefore recruitment is to be carried out at both STD and gynaecology clinics to ensure a sufficient sample size.

4 The dice method selecting those women for whom a six was thrown, as described here, was used successfully in both SASHI pilot sites, where women were being recruited from large Government ante-natal outpatient departments. In private or in smaller public clinics where fewer patients are being seen overall, more of the patients attending may need to be selected randomly (e.g. when three or six are thrown on the dice), but this will also depend on the number of researchers posted at the clinic to carry out the study.

5 In one pilot study the microbiology examination for wet preparation was being carried out far away from the clinical site of specimen collection. When a microscope was instead carried to the clinical area and microbiological examination done immediately after sample collection, the diagnostic yield of Trichomonas vaginalis increased substantially. This is a useful strategy for ensuring rapid examination of fresh samples.

6 For example, in one SASHI pilot site there were 2,110 workers on the staff roll of this factory and every 4th man was selected from this register, giving a potential sample of 530 men (of whom 508 agreed to participate).

CHAPTER 6

Ethical Issues

Introduction

This chapter discusses the ethical issues associated with studying sexual health, in general, and by utilising the methodological approaches recommended for undertaking SASHI, in particular. It sets out the ethical principles which need to be observed and the procedures which are recommended in order to ensure that SASHI is carried out in accordance with internationally accepted and locally appropriate standards for work in this field.

General principles

SASHI deals with the sexual health of people, and almost all steps of SASHI involve collection of highly sensitive information from or about individuals.

The key principle must be to ensure that no harm is done to individuals through SASHI. This includes physical damage, mental distress and disruption to social relationships.

What are the potential dangers that need to be avoided? For example, data identifying individuals engaging in high risk behaviour could be leaked to the press or the police and could lead to the discrimination and stigmatisation of individuals or of whole groups or communities of which these individuals are members. Workers might be treated unfairly because data on their sexual health might become known to employers. Patients could be urged to participate in potentially painful examinations without being told that they may opt out of the study without any disadvantage to them.

Avoidance of harm to individuals and communities is not only the responsibility of SASHI Project Coordinators, Supervisors and Resource Group members, it should also be guaranteed by institutions initiating the SASHI process and having ownership for the data collected, such as State AIDS Societies or NGOs.

Procedures and practices for ensuring ethical standards

The following issues need to be observed:

— ***Commitment to intervene:*** It is unethical to expose individuals to the SASHI process if the data collected are not translated into appropriate interventions where these are found to be necessary. SASHI is not an end in itself, and the political and financial commitment to launch interventions if these are found to be needed, and to review the appropriateness of any existing interventions, should be in place before SASHI is commenced.

— ***Clearance:*** This SASHI package adheres to the regulations on the ethics of biomedical research of the Indian Council of Medical Research (updated in 1998). If committees for the ethical review of medical and/or behavioural study proposals exist in a particular state, institutions initiating the SASHI process should approach such committees to obtain local clearance.

— ***Informed institutional awareness:*** Institutions, NGOs and authorities collaborating in SASHI or directly concerned with the implementation of SASHI should be informed about the objectives and the major details of the SASHI methodology, and through this process it should be ensured that they are aware and in agreement with the implementation of SASHI.

— ***Informed individual consent:*** Participation in any research is voluntary. This applies to both medical and social science studies, and to individuals as well as groups (e.g. in a focus group discussion).

— Voluntary participation must be based on informed consent. This means that participants need to understand the objectives and procedures of the study, and that the information given to them is correct and clear.

— Informed consent should be given in writing whenever this is feasible and culturally acceptable, using proformas such as those developed and piloted for this package (for example those in *Data Collection Guides E1, E2 and E3 in Appendix 5.1*). This is particularly important for invasive investigations such as clinical examination. However, verbal informed consent does suffice if these conditions are not met. In this case, the investigator should document that verbal consent has been obtained.

— Study participants must be informed about their right to terminate participation in the study at any time without any disadvantages such as losing access to health care benefits or other services.

— Behavioural observations do not require explicit consent of individuals or groups under investigation. However, if asked, the investigator should disclose his/her role and interest.

— ***Confidentiality:*** Data on individuals must be kept strictly confidential and participants must be assured of this. Names of study participants should be detached from data sheets as soon as possible and destroyed. In the case of the workplace based study (male general population study), the identity of the institution from which recruitment takes place must be kept confidential.

— ***HIV testing:*** In the context of SASHI, any HIV testing should be anonymous and unlinked, and should only be performed if requested or approved by the State Government body responsible for HIV/AIDS policy (usually, the State AIDS Cell or Society). If a study participant wishes to know his/her HIV status, a (separate) serum sample should be obtained for individual diagnostic purposes after appropriate pre-test counselling. Results must be kept confidential, and should be disclosed to the individual only together with post-test counselling.

— ***Feedback of test results:*** Results of testing for treatable STDs need to be made available to patients and clinicians promptly wherever feasible. For example, procedures must be put in place so that patients with positive bacteriological result for gonococcal infection will have a chance to be treated within a few days. On the other hand, if certain special tests (such as LCR or PCR) can only be performed after specimens have been collated over a period of several months, or take a long time until completion because they require that specimens are sent to a specialist laboratory, there would not be a strict obligation to make these results available to study participants.

— ***Feedback of other information and guidance towards further assistance:*** Individual study participants or patients who are found to have problems with their sexual health or who request help on a certain health or other matter should be given adequate information on where and how to access treatment, advice and other assistance within the local setting.

— ***Surrogate client visits:*** Surrogate or dummy client visits to treatment providers (including medical practitioners) can provide extremely useful information on the provision and performance of services, but it has been argued whether such visits are ethically justified. In the context of SASHI, surrogate client visits are needed to determine current practice and identify the need for improvement in the quality of medical services, so as to enable the planning of specific interventions for the benefit of the public. Surrogate client visits can, therefore, be compared with quality control procedures targeted at, for example, food producers or restaurants. Data on specific establishments (e.g. clinics or individual practitioners) must be kept confidential, and reported in an unlinked and anonymous way. This also includes information on professional errors or mistakes of providers which become apparent during the application of the SASHI package. Such information can be reported to the health authorities of the particular community or State by referring to the overall sector or medical system concerned, without revealing the identity of individual treatment providers.

— ***Medical procedures in surrogate clients:*** It should be left to the surrogate clients (male only in the SASHI protocol) to decide for each specific situation whether or not they want to accept a genital inspection. However, it is strongly recommended that they are trained to refuse any invasive diagnostic or therapeutic procedures (such as taking of injections), as these may potentially cause bodily harm. Written informed consent should be obtained from surrogate clients before they embark on visits.

— ***Data recording:*** During implementation of the SASHI package, a large amount of data are generated. It would be unethical for these data to be collected without being properly recorded. Therefore, great care must be taken to document all data carefully. Occasionally it will occur that collected data are incomplete. Although the completeness of data is of great importance, it would be unethical and dangerous to invent data in order to ensure that data sheets look complete. In such a case data must instead be recorded as missing.

CHAPTER 7

Data Recording and Monitoring

Introduction

This chapter describes procedures for the recording of medical and social science data as part of SASHI. SASHI can be implemented at different levels of complexity, as described in detail in Chapter 2. The guidelines provided here cover all the data that would be collected if the most comprehensive SASHI option were implemented, based on procedures that were developed and refined during the SASHI pilots. If a simpler version of SASHI has been implemented, then the references which relate to the steps which were not carried out will not be relevant. Monitoring of social science and medical data collection procedures are also covered in *Chapter 9* and in *Appendix 9.1*, which provides a detailed list of the responsibilities of the social science and medical team supervisors and also formats for preparation of weekly data collection reports.

Recording of medical data

Medical (epidemiological/clinical) data are recorded in a structured way on the *data recording* forms which are provided in *Appendix 5.1* of the Protocol (Chapter 5). It is crucial that such data recording is both accurate and complete. Data which are not properly recorded may as well not have been collected. The collection of data which are not recorded properly is, therefore, a waste of resources and an imposition on people who give up their time and allow researchers to obtain sensitive information and (in the case of the medical studies) perform invasive examinations from which no benefit to the community is obtained. Such activity is unethical as well as wasteful. Improper data recording includes: failure to record data; incomplete data recording; inaccurate data recording; or recording data which have not actually been collected (for example guessing answers to questions which were not asked and recording these as real data). The importance of and techniques for data recording should be covered in detail during the training period and should be field-tested during the pilot period.

Medical data entry and data checking

Data entry for the medical component of SASHI by the data entry clerk should commence during the data collection phase, so that the data are ready for analysis as soon as possible after the completion of a data collection exercise and it is possible to complete the report quickly and ensure rapid feedback of the SASHI findings to intervention planners.

Use of EPI-INFO computer package is recommended for both data entry and data analysis of the medical data. EPI-INFO is a simple package with an easy to understand manual which allows for self-teaching. EPI-INFO is widely available and can be obtained at low cost from the World Health Organisation. If EPI-INFO expertise is available locally this could also be utilised.

EPI-INFO allows the computer file versions of questionnaires and data recording forms to be converted into data-entry programmes. The questionnaires which form part of the medical data recording forms provided in *Appendix 5.1* of the SASHI protocol are also provided in computer file format in this package, in Word for Windows and ASCII formats. Editing of these questionnaires and data recording forms will occur during the process of adapting SASHI to local contexts, and the disk versions of final questionnaires and data recording forms can then be converted into data-entry programmes.

'Logical' checks can be incorporated into the data entry programmes: this means that the programme can be made to alert the person entering data if there is a logical inconsistency in the data which are being entered, such as, if 'vaginal discharge' is being recorded for a male patient. Range checks can also be incorporated, which alert the person entering data if they attempt to enter a number which is not a permissable value.

Monitoring of medical data collection and data entry procedures is covered in *Chapter 9: Management and Coordination* and particularly in *Appendix 9.12: Supervision procedures for medical components*. These set out the responsibilities of the SASHI management team generally and the supervisory responsibilities of the medical supervisor in particular. Appendix 9.12 provides a detailed checklist of the medical supervisor's duties and also a model format for the weekly reporting of the medical data that are collected during SASHI.

Recording of social science data

Recording social science data is a more complex task than recording the medical data because most of the data involved are qualitative. The steps required to ensure accurate and complete recording of social science data are provided below. Analysis of data from all aspects of SASHI and the production of a SASHI report are then described. Further details of the supervisory and managerial procedures involved in monitoring the collection of social science data are provided in *Chapter 9: Management and coordination* and particularly in *Appendix 9.1*, which provides a list of supervisory responsibilities and a model reporting form for the weekly reporting of social science data. The section below on supervision of social science data collection should be read in conjunction with these parts of *Chapter 9* and *Appendix 9.1*.

Social science component of SASHI requires collection and maintenance of complete and accurate records of data about sexual behaviour and about perceptions and practices relating to reproductive and sexual health collected from existing sources, officials, health providers, key informants, STD/RTI patients, community men and women, individuals

practising high risk behaviour and members of vulnerable populations. Social science researchers must collect, record, transcribe and translate information gathered through different data collection methods including semi-structured interviews, group discussions, participant observation, informal observation and social mapping exercises. Information will be collected regarding (i) localities and places associated with high risk sexual behaviour and where people obtain treatment for STDs, (ii) sexual behaviour and perceptions and practices relating to reproductive and sexual health of local people and those likely to be at particular risk of STD/HIV infection and (iii) the kinds and quality of treatment people with STDs get. The social science supervisor collects some of these primary data, guides the rest of the social science team in their activities and also, reviews, monitors and helps in coding of these data.

Data recording by Social Science Field Researchers

All field researchers will record the data that they collect during different steps of stages B, C and D of the protocol in two physically separate places; their Field Diary (a notebook which is easy to carry in a pocket or bag) and the Data Recording Forms (provided in Appendix 5.1). Record all notes (taken during or immediately after data collection itself) initially in the Field Diary and then use the Data Recording Forms to write up fair and complete records of all the data that have been gathered. The Field Diary itself should include the following three types of notes:

(i) Activity log - a log (or list) of daily activities, stating which field visits and data collection activities have been completed. This should include the location of data collection and exactly when this was done (date and time). For ease of reference this can be entered separately from the field notes, using the back pages of the Field Diary.

(ii) Field notes. These are initial notes of primary data made at all stages of data collection, that is during and/or immediately after visits, interviews, discussions and observations of all kinds. These notes form the basis of the written up version recorded on *Data Recording Forms*. Field notes can be divided into three kinds:

— Ethnographic or descriptive notes

These are descriptive, concrete details of all the information gathered from each source, using quotations that give participants' views and statements as far as possible in exactly their own words, along with observations of processes (e.g. willingness to talk or reluctance to speak on a particular issue) made by the researcher during data collection. Whilst writing, a clear separation between description and interpretation or judgement should be made and the latter recorded separately (see next point below). It is important also to note down observations of what happens in a group, what people say, what they do, how they interact and the nature of the physical setting, variations in activities and in the extent of agreement or disagreement on a topic in group contexts. Silences and differences between what is explicitly said and other indications of reactions should also be recorded; for example

a program manager's verbally positive ('oh, we promote such things') but physically negative reaction (looking away, suddenly pretending to read some paper on the desk) to a question about condom marketing.

— Notes that record the views of the fieldworker or provide an analysis of social situations

The experiences, thoughts, feelings and observations of fieldworkers should be recorded. Reactions to the experience and reflections about the meaning and significance of what has occurred - and how these can affect the interpretation of what has been observed or heard - should also be recorded. Insights, interpretations, initial analysis and working hypotheses of the information which is being collected should also be added to these notes, including thoughts about what the information gathered might suggest, how this could be verified and further questions arising.

— Notes on method and technique used

Experiences of using data collection guides for different stages of SASHI - which methods worked, successes, failures and modifications made - should be recorded, for future modification and use. For example, if a particular type of question or topic indicated in a data collection guide produced a hostile response, but the information was subsequently obtained more successfully by using a different line of questioning, these observations and adaptations should be noted. Also, always, record both whether any other persons were present (for example during an in-depth interview) other than the main informant and if so, who; and whether any other persons helped to initiate the interview, group discussion or other activity (for example, an anganwadi worker who provided introductions to a community member who was then interviewed).

(iii) Follow up points - a list of points for follow-up should be listed daily in the field diary for the next day's activities, including both *questions* which need further investigation (for example, when two different interviews have produced different local names for a particular sexually transmitted disease) and *activities* which will be needed. Activities needed may relate to *people*, for example, when the name of a new private practitioner who will need to be interviewed is revealed during an interview or group discussion, or to *places*, for example, when it is reported that sex workers are active in a particular part of the city, which will necessitate a field visit. In the points on people, also record possible routes of access to different informants, such as contact persons and places.

For each fieldworker, the sequence of steps for recording these different kinds of data will be:

— Collect data on the topics described in the relevant *Data Collection Guide (Appendix 5.1)* for that particular step (memorise these guides as far as possible; after the first couple of weeks of data collection you will naturally become familiar with and able to recall them)

— For each activity, record in your Field Diary all conversation and other orally presented information as far as possible verbatim (that is, the exact words used by informants,

particularly local terms for behaviours, persons, symptoms, illnesses, body parts and other items relevant to sexual health-related matters). In formal interviews, group discussions and other situations where it is possible to make notes openly, record as much as possible of the informants' exact words and make brief notes of other points, phrases, observations and revealing moments which will help you to recall and fill in the details afterwards. In other situations where it is difficult or inappropriate to make notes during data collection, make field notes immediately afterwards, recalling and recording as much detail as you can remember. For every activity which involves conversation or contact with an informant, make sure to note how and where you contacted them (for example, started a conversation while waiting for a bus at place x; was taken to their house by the local anganwadi worker; had asked an NGO to arrange for them to convene at their community centre, etc.).

— At the end of each day's fieldwork, complete an activity log in the back of your field diary giving details of visits made (locations and addresses), persons contacted, successes and failures of the day, contacts developed, if any, and any other information that may be useful for SASHI.

— Each day make and maintain a list of points and activities to be followed up subsequently or leads to be taken up with respondents during next visits. Enter this list of follow up points into the field diary after completing that day's transcription of field notes (see below).

— As soon as possible after completing a data collection activity and in all cases within 24 hours, write up the field notes recorded in the field diary in full on the appropriate *Data Recording Form (Appendix 5.1)* for the relevant step for that activity. Field notes must be written up promptly in order to maintain as total recall as possible and thus the quality of the completed account. If fluent in written English, translate data that were recorded in the local language in your field notes into English at the time of writing up. Retain the original local terms for names of diseases, treatment methods, terms used to describe a health condition etc. but record these using English letters in parentheses (brackets) next to the English language translation of each word. If not competent in written English, write up the data in full only in the original language on the relevant *Data Recording Form.*

— Code each *Data Recording Form* in the boxes marked *Code No:* in the right hand corner, as follows:

The field researcher who collected and wrote up the the data on the form enters his/her name initial in the first box[1].

The same field researcher enters the letter of the alphabet corresponding to the stage completed in the second box and the number corresponding to the step completed within that stage in the third box.

The social science supervisor enters a three-figure serial number of the data sheet in the last three boxes, starting with 001 and assigned chronologically according to when the otherwise completed form is handed in to the supervisor at the project office.

Example: 'Anjali Bawa' collects data from men who have sex with men. Thus the first box will be coded as A. The stage for the data collected is C (these data would be collected in step **C5**) and so the second box will be coded as C and the third box as 5. If this is the eighth data sheet completed and handed in, the supervisor will code the last three boxes as 008. The complete unique code for this particular data recording form would therefore be: AC5008.

Recording different types of social science data

During the three stages of active primary data collection in the field - (**B: Site mapping**, **C: Data collection on sexual and health behaviour** and **D: Study of RTI/STD services**) - the tools of data collection primarily used are interviews, group discussions, social mapping and informal and participant observation. Specific points to note when recording data for each of these components are described here.

— **Interviews :** A range of kinds of interviews are used within SASHI during different data collection steps. *Data Collection Guides B1, B2, C4, C5(i), C5(ii)* and *C5(iii), D2, D3* and *D5(i), D5(ii)* or *D5(iii)* in *Appendix 5.1* of the protocol (Chapter 5) provide guidelines of the areas to be covered and probed during semi-structured interviews of different types, while the data that are gathered as a result must be recorded in the *Data Recording Form* of the same step number and letter. Special features to be kept in mind while recording data gathered from any of the different kinds of interviews used in the protocol are: Record the reason for choosing the informant and the route of access and/or contact person(s) which have led to this person. As far as possible record each interview 'verbatim' (word for word) with exact quotations. Make a note of the length of the interview, place of conducting it and the overall response (helpful, obstructive...) of the interviewee. Note non-verbal messages and the researcher's response separately.

— **Case histories :** An illness case history may simply take the form of an interview which is purposely undertaken to elicit, and results in, an individual illness narrative on this topic. This is likely to be the most common form of a case history within SASHI. Alternatively however a case history of illness may emerge or be compiled from one or more separate interviews with individuals or groups. (In either form the same general points for recording interview data as described above apply.) If more than one interview is undertaken purely in order to construct a single illness case history, then all the data gathered can be recorded on one data recording form. In this case it is important to record clearly the number and details of interviews that were conducted to put together this history and the people who were interviewed to complete it (family members, health providers). If however a particular case history is referred to by

different informants who are interviewed separately and who also provide other kinds of information during the course of the interview, or indeed are interviewed mainly for other reasons as part of a different step of SASHI, then treat each of these as a separate data collection activity (interview) and write up the data collected from each of them on separate data recording forms appropriate to the type of activity and step involved, but make a note on each one about where to refer to other information on the case, so that cross-referencing between data recording forms is possible. Both case histories and exit interviews should also record the initial situations which led to the current complaint/problem, the stages in the life history of the person relevant to the complaint, the motivations or constraints faced by the person, the episodes of treatment seeking and their views and perceptions having experienced the problem.

— **Observations :** Record informal observations and participant observation following the guidelines provided in *Data Collection Guides B3*, *C1* and *D2(ii)* in *Appendix 5.1* respectively and write up the information gathered in the form of field notes on the relevant *Data Recording Form*. Both quantitative and qualitative observations should be recorded (e.g. number of health facilities, number of providers, number of pharmacies, sources of condoms, location of condoms, number of people at a particular pharmacy or place and physical lay-out and furnishings of particular sites, interactive behaviour between sex workers and clients, kinds of people at public sites or near particular locations).

— **Social mapping :** Record the information and maps produced from social mapping using *Data Recording Forms C2* and *C3* in *Appendix 5.1*, based on field notes taken at the time. Record the circumstances in which the social mapping was undertaken and how the group was convened (e.g. by prior arrangement through a local NGO, or, spontaneously after initiating discussion with a group of women who happened to be gathered at someone's house). Record the material used for mapping (floor, chart paper, pens, chalk, rangoli powder..) and also the place chosen, by whom and the roles taken up by different members. Note in detail dynamics/processes during mapping - which topics were chosen easily, to which there was a negative response or reluctance to discuss (for instance, access to services - allopathic, local medical college, certain providers). Record relevant reactions and responses of observers and others who were drawn into the discussion too.

— **Group discussions :** Write up field notes of group discussions with women and men using *Data Recording Forms C2* and *C3* (*Appendix 5.1*) respectively. While recording group discussions, special note should be made of the following points: Number of participants, sex, age and other features of the participants (e.g. from same *'basti'*, parked taxis in same stand), how they were collected for the discussion, dynamics noted in the group during discussion (roles different members played - leader, moderator), members' reactions to different topics of discussion, members' lack of response to certain topics, and researcher's observation of non-verbal messages, body

language, additions and temporary absences from the group. If a core group continued discussion with other members joining and leaving intermittently, then record the number and features of such members and reasons for these individuals leaving the group. Always record actual verbatim responses of members during the discussion whenever possible. When recording discussions with men at high risk, note the route of access to such men (e.g. through local *pan wala,* through local union organizer, through researcher striking up casual conversation with some of the participants, etc.) and also record the reasons for choosing the site for discussion and the details of the site (physical location such as: in the centre of the community if participating men live in the same residential area, a temple or popular tea stall near their place of work).

Data recording and monitoring by the Social Science Supervisor

The social science supervisor will undertake primary data collection together with the other members of the social science research team, following the guidelines for data recording described above. In the initial stages particularly, the supervisor should pair up with a more inexperienced member of the social science research team to help their ongoing training in the field and so that the more junior researcher can learn from the supervisor. As described here, the supervisor will also monitor on-going data collection, review tasks periodically and help the field researchers to code and file the data and, where necessary, translate or arrange translation of the data collected during the different stages. The supervisor will also take responsibility for overall strategic decisions concerning the data collection process, such as judging when to cease work on a particular data collection step after balancing time constraints with the adequacy of the information already collected, or whether to continue investigation of certain areas which may be particularly fruitful although this may require selective reduction in other activities.

The data collection and data recording process are closely knit together and are an on-going process throughout the project. Data recording process in the area of qualitative research on sexual and reproductive health must be closely linked to reviewing the data collected so far and identifying future leads for follow-up. To facilitate this iterative process it is necessary that the supervisor monitors the activities of the social science field researchers activities regularly; this monitoring forms part of the supervisory duties that are listed in *Appendix 9.1* of *Chapter 9* on the Management, Supervision and Coordination of SASHI for the Social Science Supervisor and that should be referred to in conjunction with this chapter.

In addition to overall supervision, which encompasses many elements relating to the data collection and recording processes, there are specific monitoring tasks which should be carried out by the social research science as follows:

— Check each data recording form for completeness as it is handed in and enter the serial number of the code (last three boxes, as described above for the social science field researchers).

— Translate those data recording forms which have been written in the original language into English, or if not competent to do so, arrange for this task to be done by a competent person as the data collection proceeds and the forms are completed. Make sure the original language term is recorded in brackets after its English translation whenever a new or technical word has been used. Record the completed translation on the correct *Data Recording Form* for that stage and step of data collection (e.g. B3, D2) and give the form exactly the same code as the original language version.

— Arrange for all data to be entered into a computer using an appropriate word processing package. As far as possible, ensure the data are entered as they are collected and written up. Ensure each data recording form is entered as a separate file and labelled by the code number of that form; in the computer keep separate folders for all the files corresponding to the same data collection step.

— Once the data have been entered into the computer, store the original *Data Recording Forms* in a secure place, keeping separate folders for each stage and step of data collection (filing could be by letter and number of the step - e.g. *D5* for exit interviews with STD patients).

— Plan and convene regular weekly meetings which every member of the research team attends to share experiences, to discuss problems and possible solutions, and to review progress of data collection. Based on the meeting, draw up the schedule for the next weeks work in collaboration with the rest of the research team and agree on division of labour between the researchers for the different steps and follow up activities to be undertaken.

— In each weekly review meeting, coordinate the team in summarising the information collected, understanding the data collection process and deciding on next steps. A useful strategy is to use large sheets of chart paper divided into three columns headed, 'Type of Activity', 'Information Gained' and 'Next Steps' (or 'Questions Arising'). Ask fieldworkers to record with coloured marker pens the code (letter and number) for each step undertaken during the preceding week in the first column, a brief summary of the kinds of information gathered (for all the data collection activities falling under that step that were completed in the past week) in the second column and, following discussion of these findings, the implications for what to focus on finding out next, from whom and where in the third column.

— Look for gaps in the information collected by reviewing the completed *Data Recording Forms* frequently and ensure that these gaps are filled at the earliest possible opportunity. Sometimes these may be omissions from the writing up of data that have been gathered by the field researcher(s) but not fully recorded. Hence the supervisor should review incomplete or sketchy transcripts of field notes with the relevant researcher(s) as soon as possible and ensure that any missing information is added to the forms. However gaps may also be on topics or questions that are given in the data collection guide but

have not been covered in the field work, or new or unexpected points that emerge from the field work. For example, a new or unexpected point might be a comment from an informant in one interview that suggests a new sexual network or setting for high risk sexual activity that had not been identified before. Even though the interview was mainly intended as an illness case history, for example, the comment should be followed up, for instance by a repeat interview of the same informant or by focused questioning of other informants during subsequent data collection activities to explore this topic and verify or discount the new information.

Note :

[1] Review each team member's initials at the start of data collection and if more than one name starts with the same letter, choose a different name (e.g. family name) for one of the researchers so that each team member has a unique letter. Often pairs of researchers carry out data collection together, in which case the individual researcher who actually transcribes the information on the Data Recording Form afterwards should code the form using his/her initial.

CHAPTER 8

Data Analysis and Report Preparation

Introduction

This chapter describes how the social science and medical data collected for SASHI can be analysed, and sets out the steps and responsibilities involved in report writing. Suggested formats for the contents and layout of the social science and medical components and for the overall SASHI report are provided, based on the experience of preparing reports on the findings from the SASHI pilot sites. These formats cover all of the data that would be collected if the most comprehensive SASHI option were implemented; if a simpler version of SASHI (such as the 'Basic' option) has been implemented, then the sections which relate to the steps which were not carried out should be omitted. Strategies for interpreting and prioritising the SASHI findings, in order to assist their use by planners, are also discussed in this chapter, because drawing out the implications of findings for prioritising interventions is particularly important if SASHI is to be of practical value.

Data analysis

For the SASHI data which are collected to be useful, they need to be analysed appropriately and carefully. The process of data analysis, however, is quite different for the social science component, which involves mainly qualitative data, and the medical component, which involves mainly quantitative data. These are therefore considered separately, followed by guidelines on writing reports for each of these components and then finally on combining and interpreting the findings from SASHI overall.

Analysis of social science data

Because the data collected in the social science component of SASHI are mainly qualitative, they need to be examined and partially analysed as they are being collected, so that approaches to and settings for data collection can be continuously reviewed and adjusted. In fact this is essential to ensure the gathering of accurate, relevant and good quality data. Qualitative data analysis in the social science component of SASHI should therefore be an ongoing process, which means that the supervisor should read the completed data recording transcripts periodically, in order to review progress in data collection, to decide on the most beneficial direction and focus of subsequent data collection activities, and to keep track of emerging themes. These objectives are also achieved through discussions with field researchers at the weekly meetings, where clarifications may be sought and further lines of enquiry discussed. The supervisor should take primary responsibility for

data analysis with advisory input from expert members of the Resource Group, but review of findings, identification of emerging themes and, at the end of the data collection period, coding of data, could also be carried out by around two other members of the social science research team.

Although preliminary analysis should be carried out during the data collection process itself for the reasons just described, the bulk of intensive data analysis will still need to be carried out towards and immediately after the end of the main data collection phase once the information gathered can be reviewed as a whole. By this time the researchers and the supervisor should have a thorough familiarity with most of the data and will already have built up quite clear ideas of the main themes and issues that have been emerging. These can guide the subsequent data analysis activities. Following steps may help in analysing data:

— Read and re-read the data collected from different sources as they are written up.

— Identify the emerging themes, keep track of them and follow them up in subsequent data collection (for example, if men report indulging in sex without cash transactions, in further data collection on this topic probe on the theme to find out about sex partners, contexts of such interactions - say, male migration - and risky behaviour).

— Look for new or unexpected findings (for example, a report about older married women paying for sex with younger unmarried men, or about a surprising context in which nonpaid sex occurs). These should be verified from different sources. Try to gain confirmation of 'second hand' or unverified information, either by obtaining reports from 'primary' ('first hand') informants or through direct observation, or if this is not possible at least by obtaining confirmatory reports from several different and discrete sources which independently corroborate one another (sometimes referred to as 'triangulation'). Treat information with caution until it is confirmed thoroughly, or report it as tentative (see section on report writing).

— Identify common themes that run across different types of material collected through different data collection methods and from different types of informants. Develop a classification scheme for the types of information collected (for example, high risk sexual behaviour may be examined separately for men and women in heterosexual and those in same sex relationships, or there may be common themes running across these categories). Note in particular that analysis needs to cross-cut the different data collection steps of SASHI, as many topics and themes are covered in more than one step. Therefore, although it may be useful to analyse all data recording forms for one step together (in order to discover key themes and characteristics concerning, for example, commercial sex workers), it will also be essential to code across this and other steps since themes such as condom use, or types of risky sexual behaviour, or factors contributing to vulnerability, will be found in this and various other steps.

— Find interlinkages among the themes (for example, see how risky sexual behaviour is linked to barriers identified to condom use).

— After becoming thoroughly familiarised with the material, start coding a section of the data (for example, a cross-section of the transcripts) by developing categories for themes and subthemes that have emerged from the reading as potentially important for sexual health (for example, a code may be developed to denote information concerning condom use (a theme), with separate sub-codes for information concerning condom use by men within marriage and outside of it. These may be denoted by letters CU1, CU2 etc.).

— Count instances of occurrences in the data in order to get a rough estimate of frequency and generality; for example, the number of informants who have mentioned a particular symptom of STD infection, or the number of times a specific characteristic of commercial sex transaction is mentioned. Also try to form a rough estimate of the size of populations who have been a focus of data collection (e.g. number of female commercial sex workers and number of these who are street based, number of men in a vulnerable occupational group found in the site), since this will be very important for planning purposes. Use this to construct a rough ordering of significant findings in terms of their likely generality and significance in relation to other issues identified, that can be used for prioritising implications and recommendations once the primary analysis is completed (see section below on the overall SASHI report).

— Go through the chosen data, coding all the material into the developed coding categories and try to refine the coding scheme by adding, expanding, or collapsing the categories such that the codes fit the data meaningfully and not mechanically. Once the coding scheme has been refined and appears to fit different types of data well, code all the remaining social science data using this refined coding scheme. This can be done either manually, by computer, or through a combination. A manual approach is to use hard copy printouts of each data recording form, writing the chosen code for each relevant topic category in the margin next to where mention of this topic appears in the transcript and recording a note of the location (code number and page or line number of the data recording) either on index cards or in a computer file on the relevant category. If done on computer, a similar coding procedure can be followed with codes being inserted next to the relevant text position of the reference, or the relevant quotations or observations can be copied and excerpted into a separate computer file on that topic category. If the supervisor and/or other members of the research team are familiar with qualitative data analysis using a software package then data should be entered into this package when it is first typed up into the computer and subsequently coded and analysed using this package. The main advantages of this approach of using a designated software package, called computer-assisted analysis, are to manage large amounts of data efficiently and to undertake complex analyses

where formal methods (such as pile sorts) have been utilized that require semi-quantitative analysis. Such formal social science methods are not included within the SASHI protocol. Therefore, if during data collection only fairly limited amounts of social science data have been collected (such that researchers can familiarise themselves with all the data reasonably well by reading over the completed forms several times), or if researchers are not familiar with an appropriate software package in advance of undertaking SASHI, the time spent in learning the package and coding the data will outweigh its value for analysis and therefore formal computer-assisted analysis should not be attempted.

— Prepare a rough draft of the analysis and discuss with chosen experts such as appropriate members of the SASHI Resource Group or key informants to refine the analysis and to examine it in the context of settings in which data were collected. For instance, look at the findings in the context of people's socio-economic living patterns and cultural beliefs to see whether aspects of the broader context can help to explain some of the empirical findings. For example, are certain types of difficulty that have been reported in obtaining medical treatment common to informants from certain social class backgrounds or living in particular geographical locations, or who share similar ideas about the causes of sexually transmitted diseases? In other words, do not rely on the contents of the information alone but relate the circumstances and characteristics of the sources to the information obtained in interpreting this information.

Analysis of medical data

Unlike the social science data, the medical data are mostly quantitative and therefore once a study has started, its format (for example, of the questionnaire or the clinical procedure involved) cannot be adjusted or revised because this would prevent strict comparability of the information gathered. There is therefore less need to analyse the data in an ongoing way as it is not necessary to feed this back into the data collection process itself. However, there is no need to wait until all medical data collection activities have been completed before commencing analysis. Once a data collection step is complete - for example, when 50 male STD patients have been recruited - analysis can commence on this component of the study. This will allow the team to develop skills in data analysis and reporting and thus contribute to the rapid completion of the final report once SASHI data collection has been completed.

Coding of some variables may be necessary. For example, after all the data have been collected and reviewed, occupation should be recoded to summary groups (e.g. unskilled labourer; professional; student) rather than maintaining separate codes for every actual occupation recorded on the forms. If other questions have been asked that produce answers which require coding this should be carried out in a similar way.

Initial data analysis should consist of the simple listing of each variable, to check that all the entered numerical values are legitimate (that is, they are plausible numbers that could be

obtained in reality). Illegitimate values should be checked back to the original data collection forms to see if transcription errors have occurred at the data entry stage.

Recoding of variables can then be carried out. For example, age should be recoded into appropriate age groups (e.g. 15-24; 25-34 etc.) for descriptive purposes. It will then be possible to say both, the average age of the patients within each study and their proportion into each of the specified age groups.

Simple tabulations should be produced in line with the format of the report, of which a suggested outline is given below in the next section of this chapter. For example, the proportion in each marital status group, each education group, each symptom group, etc. should be produced for the male STD, female RTI and ANC studies. Cross-tabulations should then be carried out as necessary, for example cross-tabulating reported symptoms with PCR results in the male general population study.

As analyses are carried out the findings should be considered in the light of what is already known about the epidemiology of STDs in the local population. Any findings which are unexpected should be checked and sources of possible error investigated. For example, if the prevalence of chlamydia is higher in the general population studies than in the studies of people with STDs/RTIs, the performance of the laboratory test should be reviewed for possible sources of inaccuracy.

Report preparation

Once the SASHI data have been analysed, the findings need to be summarised in a written report which can be read by policy makers and others who are involved in planning and developing interventions to improve sexual health. It is important that reports which are produced can be read by non-experts and that the key messages and recommendations for these reports are simple to extract. The more complex and more technical the report, the less likely it is to be read and to have any influence on intervention development. Verbal feedback, both informally and formally in workshops, should also be given to a range of interested audiences, including all the potential beneficiaries or stakeholders of SASHI. Such verbal presentations can be based upon the written reports which are described below.

Preparation of social science report

— Prepare a report setting out the main findings according to a planned format and structure as suggested below. The report should be prepared mainly by the social science supervisor in consultation with the Local Coordinator, with assistance in preparing data and where necessary, drafting sections on particular topics from other members of the social science research team and with advisory input and guidance on analysis and interpretation of the findings from appropriate members of the Resource Group.

— Review the initial draft report with careful attention to possible sources of bias for each finding that is reported and evaluate the validity of findings in relation to these. In the report, avoid over-generalising and instead make sure to specify the sources on which a finding is based and the degree of confidence that can be placed in an assertion. Always note the limitations of an apparent finding where this is appropriate; for example that a particular piece of information was obtained from a single source and could not be verified independently, or that three out of seven informants of a particular type mentioned a particular issue whereas the others did not, together with an interpretation that takes into account the circumstances under which the information was obtained and judges its veracity accordingly. Making such judgements requires being familiar with the information available and the contexts in which it was collected and also critically examining its validity from all possible angles. Thus it cannot be easily described but is none the less an essential part of the analysis and writing up process. To use the previous example of three out of seven informants of a particular type who mentioned a certain issue, perhaps these three informants were individuals with whom the researcher had already built up a good relationship and who provided this information in a private setting after several previous meetings, whereas the other informants who did not mention this issue were each interviewed on a single occasion in a semi-public setting which did not encourage revealing detailed or intimate information. In this case, it is probably wise to place some confidence in the validity of the information provided by the three informants, despite the small numbers of reports involved. Conversely, if a sole male informant has claimed that a friend told him about certain types of women who work in the sex industry, for example, this information would need to be supported from other sources in more detail and more directly before it could be considered worth including in a report, since in this form it is potentially unreliable.

— Review the previous tentative ranking of findings and observations in their order of significance after checking for sources of bias and divide observations between those which are well substantiated from a range of sources and those which are tentative indications that require more investigation. Develop a set of recommendations for intervention and further follow up, based on this ranking of findings to go into the overall SASHI report (see below).

— The report will form one part of an overall report on SASHI combining the findings of both the social science and medical components, a format for which is provided at the end of this chapter. A possible format for the social science part of the report is given in the next section. This should be adapted as necessary according to local circumstances and key concerns and also to suit the SASHI option has that been utilised in the site. The following format is drawn up based on the SASHI pilot studies which employed the 'comprehensive' option.

Suggested structure for the report on social aspects of SASHI

[Note: SASHI Rationale and Objectives will be covered in an Introduction for both social and medical aspects of SASHI in the overall report, for which a format is proposed below]

I. Specific Objectives for the Social Component of SASHI

— List the relevant objectives (see Protocol, Chapter 5)

II. Methods of data collection

— Methods Used : (list the methods used in each stage and step - e.g. site mapping - and for particular populations - e.g., group discussions were used for men in specified occupations at high risk)

— Sources of Data : (summarise the secondary as well as the primary sources of data, including details of sociodemographic nature, income and occupational groups from whom data were gathered and describe the general sites where data collection was conducted).

— Details of Data Collection : In an *Appendix,* provide a table containing the detailed information on each data collection step, including for each of these the data sources used, the information gathered and the number of data collection activities carried out. For example, under the heading 'C3: Group discussions with men at high risk', list at the top of the table the total number of group discussions conducted and below this, list in the first column the participants in each discussion (such as 'sheet metal factory workers'; 'male college students living in hostel', 'taxi drivers' etc.) and in the second column, a summary of the types of information collected in that group discussion (e.g. 'about pimps, socio-economic position of CSWs, rate, age range of high risk groups, information about clients, information on group sex, local terms, condom use, MSM'). Compile the same information for each data collection step so that a summary of the entire data collection process is provided in this table.

III. Location of SASHI [give the name of the site]

— Key aspects of the geographic location of the site where SASHI is carried out (such as size and topography of the site, main residential areas and patterns, landmarks and key features)

— Socio-demographic background of the site (based on census reports, health surveys and state or district level survey reports; give available information on population size, sex ratio, mortality & morbidity data, fertility ratio, main occupations, social class, ethnic and caste make-up of the population, migration patterns, disease profiles with special reference to STDs and HIV/AIDS and such other demographic and health indicators)

IV. Review of existing social science Literature

— Socio-cultural context of sexual behavior (based on available social science literature on health, gender, sex and sexuality; describe what is already known about the sexual behaviour, beliefs and practices of the local population; attitudes towards sex and perception of risk to sexually transmitted diseases; findings from any studies or reports on commercial sex work or other forms of high risk sexual behaviour)

— Bibliography of relevant literature (place this at the end of the report)

V. The Findings (from primary data collected during SASHI)

a) High risk sexual behaviour and networking

— Nature of high risk sexual behaviour as perceived by the respondents (i.e. what constitutes HRB, its pattern and perceived prevalence, whether it is understood to be high risk behaviour by the respondents)

— Patterns and practice of HRB (types of HRB, commercial sexual network patterns as well as those that do not involve monetary transactions, about partners in HRB)

— Locations and times of HRB (with the help of social mapping)

— Commercial sexual networking (sexual partners, their socio-demographic description and about the network involving those instrumental in maintaining it, e.g. Auto/taxi drivers, lodge/hotel owners, pimps etc.)

— High risk sexual behaviour and networks that do not involve monetary transactions (sex partners and contexts of sexual behaviour, related networks, e.g. peers).

— Populations practising HRB and those found to be particularly vulnerable to STDs/ HIV/RTIs locally: socio-demographic description, high risk behaviour practised, locations and circumstances of sexual interaction among these groups

b) Prevalence and pattern of condom use

— Condom use/sale as reported by different sets of respondents (private practitioners, pharmacists, clients of csws, STD patients and csws)

— Perceived utility of condoms as safer sex devices

— Beliefs about condoms

— Barriers to condom use

c) Perceptions of STDs/RTIs/HIV/AIDS (among men and women)

— Identification and local awareness of STDs/RTIs/HIV/AIDS and descriptions of symptoms

— Local terms used for various sexually related diseases as locally understood

— Perceptions of causes and local beliefs about transmission and prevention

d) Treatment seeking behaviour for STDs and RTIs (among men and women)

— Notions about and familiarity with types of treatment, general preferences between known treatment options and perceived appropriateness of different types of treatment in relation to recognized symptoms and perceived causes

— Treatment seeking behaviour for STDs according to both patients and providers (including home based treatment, self medication, traditional and medical lines of treatment and over the counter treatment at pharmacies), pragmatic and other reasons for making choices

— Social perception of STDs, social stigma and barriers to seeking treatments

— Perceived treatment of infection with STDs/HIV/AIDS

e) Nature and quality of care by treatment providers

— Characteristics of patients to whom treatment is provided according to practitioners

— General conditions and relative frequency of sexually transmitted diseases seen by practitioners according to report (provide in an Appendix an anonymised list of the practitioners who were interviewed, recording number of practitioners of each type of medical system and providing speciality providing treatment for STDs and reported characteristics of patients and predominant types of STDs seen by each practitioner)

— Reported and actual treatment practices during consultations

— Reported and actual advice to patients regarding safe sex, condom use, partner notification, further treatment

VI Conclusions and Recommendations

Bullet points summarising main findings and their implications for further work and for prioritising and developing interventions to promote sexual health

VII Bibliography

Attach Appendices on:

1. Summary of Social Science Data Collection Activities
2. Practitioners interviewed and reported characteristics of patients and STDs seen

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3. List of local collaborators, partners, institutions and agencies identified through initial institutional assessment and subsequently through Stage A of data collection as potentially able to take up interventions for sexual health in the site.

4. Observations on the process of carrying out SASHI, including difficulties experienced, modifications made in the protocol or guidelines and lessons learned for future activities

5. Any other detailed information which does not fit easily into the main text of the report but would help to fill out the findings and assist the evaluation of these findings by readers.

Preparation of medical report

The report for the medical aspects of SASHI should be prepared mainly by the medical supervisor, with assistance where necessary in preparation and analysis of data and preliminary drafting of particular sections from no more than two of the medical field researchers. There should also be input from the Coordinator and from appropriate members of the SASHI Resource Group on analysis and interpretation of the findings. A suggested structure for the medical report is provided below that can be modified to local circumstances as necessary. The structure should also be adapted according to which SASHI option was used in the site (the format below is for the comprehensive option and was used in piloting the SASHI protocol; where other options have been used, certain sections or findings will need to be omitted).

Suggested structure for the report on medical components of SASHI

[Note: SASHI Rationale and Objectives will be covered in an overall introduction for both social and medical aspects of SASHI]

1. Objectives of medical (clinical and epidemiological) component of SASHI

- List objectives of the medical component (from data collection protocol, see Chapter5)

2. Compilation of existing epidemiological data

- Summary of findings on HIV and VDRL prevalence rates from blood banks and zonal HIV testing centres and trends by sex and over time (place in a Appendix all data collected on HIV tests among blood donors and VDRL tests among blood donors in separate tables; list these data separately by males and females, by year, and by source, such as Government blood banks and private blood banks)

- Summary of findings and trends from data on attendence and diagnoses from government dermatovenereology clinics (place in an Appendix tables of all the data collected, presented separately for males and females, by year, and for age-specific data if possible)

- Summary of findings and trends on VDRL and HIV prevalence rates among government dermatovenereology clinic attenders (place in an Appendix tables of the data collected, presented separately for males and females, by year, and with age-specific data if possible)
- Other data located during the SASHI study period
- Summary statement of findings from routine data collection and interpretation

3. Patients seen by private dermatovenereologists

- Table of clinical diagnoses, male and female separately, recorded by the private dermatovenereologists during the month-long collection of these data
- VDRL/HIV test reports from private dermatovenereologists
- Summary of these data (characteristics of patients seen by private dermatovenereologists)

4. Male STD study

- Sociodemographic data: age distribution, education and occupational groups, marital status
- Sexual behaviour in last 3 months, for married and unmarried men separately
- Condom use, for marital and extra-marital sexual contacts separately
- Treatment seeking behaviour before attendance at which patient recruited for study
- Symptoms at presentation
- Signs on examination
- Presumptive diagnosis (before laboratory test findings available)
- Laboratory test results
- Final diagnosis, combining clinical and laboratory data
- Cross-tabulation of presumptive diagnosis with final diagnosis
- Tabulation of cases of multiple infection
- Other observations from male STD study
- Summary statement of findings and interpretation

5. Female RTI study

- Sociodemographic data: age distribution, education and occupational groups (own occupation and spouses occupation), marital status

- Sexual behaviour in last 3 months, for married and unmarried women separately
- Condom use, for marital and extra-marital sexual contacts separately
- Treatment seeking behaviour before attendance at which patient recruited for study
- Symptoms at presentation
- Signs on examination
- Presumptive diagnosis (before laboratory test findings available)
- Laboratory test results
- Final diagnosis, combining clinical and laboratory data
- Cross-tabulation of presumptive diagnosis with final diagnosis
- Tabulation of cases of multiple infection
- Other observations from female RTI study
- Overall summary statement of findings and interpretation

6. ANC study

- Sociodemographic data: age distribution, education and occupational groups (own occupations and spouses occupations), marital status
- Symptoms at presentation
- Signs on examination
- Obstetric history
- Presumptive diagnosis, if any, (before laboratory test findings available)
- Laboratory test results
- Final diagnosis, combining clinical and laboratory data
- Cross-tabulation of presumptive diagnosis with final diagnosis
- Tabulation of cases of multiple infection
- Other observations from ANC study
- Overall summary statement of findings and interpretation

7. Male general population study

- Sociodemographic data: age distribution, education and occupational groups, marital status
- Symptom reporting, overall and by two broad age groups

- Prevalence of PCR NG and chlamydia positivity, overall and by two broad age groups
- Prevalence of PCR NG and chlamydia positivity by symptom reporting
- Other observations from male general population study
- Overall summary statement of findings and interpretation

8. Additional ANC study

- Sociodemographic data: age distribution, education and occupational groups (own occupations and spouses occupations), marital status
- Symptoms at presentation
- Signs on examination
- Obstetric history
- Presumptive diagnosis, if any, (before laboratory test findings available)
- Prevalence of PCR NG and chlamydia positivity, overall and by two broad age groups
- Prevalence of PCR NG and chlamydia positivity by symptom reporting
- Other observations from additional ANC study
- Overall summary statement of findings and interpretation

9. Male urethritis study

- Sociodemographic data: age distribution, education and occupational groups, marital status
- Sexual behaviour in last 3 months, for married and unmarried men separately
- Condom use, for marital and extra-marital sexual contacts separately
- Treatment seeking behaviour before attendance at which patient recruited for study
- Symptoms at presentation
- Signs on examination
- Presumptive diagnosis (before laboratory test findings available)
- Laboratory test results
- Final diagnosis, combining clinical and laboratory data
- Cross-tabulation of presumptive diagnosis with final diagnosis
- Tabulation of cases of multiple infection
- Other observations from male urethritis study

10. Combined analyses of male STD and urethritis study
    - Overall prevalence of aetiological agents among all men presenting with urethritis during the two studies
11. Combined analyses of ANC and additional ANC study
    - Overall prevalence of PCR NG and chlamydia
    - Summary of findings on female general population studies
12. Combined analyses of NG culture and sensitivity tests
13. Quality control and test comparability
    - Outline of quality control activities which were carried out, including details of whether repeat tests were done blind to the results of the initial test
    - Quality control analyses: cross-tabulations of first and second test on the same samples
    - Cross-tabulations of chlamydia prevalence detected by EIA and PCR in the male STD study, female RTI study, ANC study and male urethritis study
    - Summary of quality control procedures
14. Lessons learned
    - Brief executive summary of overall findings of medical components of SASHI and key highlights
    - Recommendations for STD services and other initiatives aimed at improving sexual health based upon the findings of these studies
    - Observations on the process of carrying out medical aspects of SASHI
    - Recommendations for future capacity building with respect to clinical and laboratory diagnosis and management of STDs

Overall SASHI report and prioritisation of findings

The overall report on SASHI should be drafted after both the social and medical reports have been completed. The Local Coordinator and social and medical supervisors should be primarily responsible for seeing that the overall report is produced, either by preparing the report themselves or by identifying appropriate persons already involved with the SASHI study to do so. Assistance in drafting sections, interpreting findings and synthesising results of the medical and social components could be obtained from members of the research teams and substantive input on interpretation of results and development of recommendations deriving from the findings should be provided by the SASHI Resource Group. Particular attention should be paid to the need to bring together the information gathered in both the social science and medical components and to interpret these findings

in a way which allows implications for decision-making to be drawn out.

The following points for consideration may help in interpreting the various findings in a manner that will help to indicate appropriate recommendations for prioritising interventions:

- What does this result indicate about the prevalence of the problem or phenomenon in the site generally (for example, perceptions among some women in the community that condom use causes discharge; or chlamydia infection among male STD patients)? Can the finding be generalised from the participants involved in this particular component of data collection, or this group of informants, to the rest of the place/population/ gender (etc. as appropriate) in the site? If not, how far can it be generalised - are there rough limits that can be stated about the likelihood of this finding being general and reliable?

- Are there particular sources of bias or other reasons for treating this finding in a tentative way? Does this type of bias suggest that the finding is likely to hold true for areas/ groups but not for others?

- Does this finding have more or less significance in terms of its public health implications than the other findings in the study? Why?

These types of questions should be considered for both qualitative and quantitative findings (for quantitative results, formal estimates of confidence can also be made statistically by calculation of confidence intervals). Once all the main findings have been examined in this way these should be compared with one another and a rough ranking of the relative significance of the findings should be drawn up. This ranking should be in terms of those findings that are likely to be most significant in public health terms and that most strongly suggest a need either for an immediate intervention, or for further immediate work (focused studies or needs assessments) that would assist in deciding whether to launch an intervention and of what type. In the report, when the findings are presented and discusssed this should be done in as specific a way as possible, with information being qualified where appropriate to indicate, for example, if they are tentative, to what extent they can be generalised, whether (for qualitative data, for instance on a vulnerable population engaging in high risk behaviour) rough numerical estimates can be provided and if not, what further information could beneficially be gathered in order to provide such information. Final recommendations should use the rough ranking arrived at through the above exercise in comparison of the findings in terms of their robustness, in order to provide some prioritisation of the findings for use in decision making.

Suggested structure for overall SASHI report

A suggested structure for the overall report is as follows:

1. Introductory section

- Table of Contents

- Background to report; who commissioned SASHI; which institutions contributed to carrying it out; who funded the work
- Background to SASHI more generally, including detailed aims and objectives
- Full list of researchers and other team members involved in implementing SASHI
- Acknowledgements to SASHI team and to people and institutions who contributed to the successful completion of SASHI
- Glossary of abbreviations

2. Executive summary

This should be a brief (two-page) summary in the form of numbered bullet-point summaries of the key findings of SASHI, drawing on the results of both social science and medical components as provided in the separate reports of each and covering:

- Who are the vulnerable populations and communities in the area?
- What is the level of knowledge about HIV/AIDS/STDs, both generally and within particular sections of the population?
- What are the current levels of condom use both generally and within particular sections of the population (men, women, sex workers, etc.) and how could condom use be promoted?
- Are interventions focused on specific vulnerable groups or high-risk locations appropriate, and if so who and where should these be focused on?
- Which agencies treat STDs and how could treatment services be improved, with regard to both treatment and health promotion to reduce the future HIV/AIDS/STD/RTI risk of their patients?
- Which aetiological agents are seen among STD clinic attenders and what is the prevalence of mixed infections?
- How does this pattern of infections seem related to guidelines for STD management?
- What is the pattern of antibiotic sensitivity of gonococcal infection?
- What is the prevalence of infection in the general population?

3. Report on social aspects of SASHI (as detailed above)

4. Report on medical aspects of SASHI (as detailed above)

5. Synthesis, conclusions and recommendations

Information from the social science and medical components of SASHI should again be brought together and integrated in this section, especially for all topics on which data were collected in both components (such as, for example, condom use, treatment seeking

behaviour, sexual networks). Recommendations for intervention design should be made on the basis of this synthesis. The form this synthesis takes will depend upon the information that has been uncovered during the implementation of SASHI, although it is likely that the areas described above in brief under the 'executive summary' will be covered. Each of the main sections of both reports should be examined together with the key findings and considered in the light of the results from other components of the studies. Some examples of such syntheses could be:

(a) Who are the most vulnerable sections of the local population: Does the social science information agree with the profile of the clients seen at STD clinics or at other STD services? If not, are these people being missed by the services studied by SASHI or is their apparent high-risk status illusory?

(b) Projection of the threat to the community: Do the epidemiological data (trends in HIV/VDRL and general population STD prevalences) together with knowledge about vulnerable groups suggest that an increasing prevalence of HIV and other sexual health problems may be anticipated?

(c) Are opportunities for health promotion being taken: Does the counselling regarding future sexual behaviour, condom use and partner notification received by clients at STD clinics match the needs of these clients?

(d) Condom use: How does condom use of STD clinic attenders tie in with information on condom use obtained from the social science research? What are the implications of these findings and of social research information on obstacles to condom use for developing interventions to promote this?

(e) Treatment seeking behaviour: Is the information on treatment history and referral patterns of patients seen at the STD clinics by the medical researchers consistent with information from the social science component, both from exit interviews with these patients and from other information gathered in the community? What are the perceived barriers to appropriate treatment seeking behaviour and what interventions could contribute to overcoming these?

(f) STD case management: What agreement is there between what allopathic and specialist practitioners claim to do with respect to the clinical management of STD cases and what they actually do in practice? What do the data from the medical studies of STDs suggest would be the appropriate management strategy (e.g. is syndromic management indicated?)

(g) Advice on prevention and health promotion: What agreement is there between what information practitioners claim to give their STD patients with regard to condom use, partner notification and HIV transmission and what they actually provide? What do the data from the social research component on treatment providers, both pharmacists and practitioners, suggest regarding the best opportunities for providing health promoting information to STD patients and others at risk of STDs and HIV?

(h) Practitioners' knowledge and epidemiological prevalence of STDs: How far do the epidemiological findings on prevalence of STDs match the social findings on practitioners' reports of the STDs most commonly seen? If there are clear discrepancies, what are the likely reasons for the mismatch between practitioners, (mis)perceptions of which STDs are most common and the epidemiological picture? Does this have implications for effective treatment of STDs that are prevalent in the community and if so, how can more accurate diagnosis and hence more effective treatment best be promoted in the circumstances documented?

(i) Community knowledge and epidemiological prevalence of STDs: What agreement is there between awareness, knowledge and recognition of different STDs in the population generally and among particularly vulnerable sections of the population, and the epidemiological findings? Is there a need for general awareness-raising or education about STDs as a whole or do the social research findings suggest that levels of stigma surrounding these conditions would mean a general campaign is likely to be counter-productive?

Recommendations: A prioritised set of suggestions for possible interventions and areas for follow up should be made from the summary synthesis and discussion of findings, with a brief rationale provided for the nature of the interventions recommended; use the suggested guidelines above on 'testing' the validity and reliability of the various results and formulating a ranking of significance and strength of the information gathered. An explicit distinction should be made between those findings that clearly indicate the need for intervention development and implementation as a priority, and those that appear to suggest such a need but are still tentative and will require follow up (for example, through further focused investigation or a needs assessment) before the need for an intervention, or the type of intervention needed, can be fully assessed. Recommendations to carry out further work on a particular area, topic or population are quite appropriate in drawing conclusions from a general preliminary situational analysis such as SASHI which, as a first step, does not aim at detailed coverage of any one particular setting or group but attempts to provide an overview of the general situation.

CHAPTER 9

Management, Supervision and Co-ordination

Introduction

This chapter sets out the management and supervision needs for SASHI and describes the areas of responsibility of the Coordinator and Medical and Social Science team Supervisors who together make up the SASHI Management Team. Their individual duties are set out in more detail in the Appendices to this Chapter. The chapter also discusses how to deal with problems that may arise during the implementation of SASHI.

Team management and organization of SASHI activities

SASHI aims to be a rapid and efficient tool for collecting necessary data for prioritising, designing and implementing effective and locally appropriate interventions to improve sexual health of the problem. To achieve this goal a comprehensive battery of investigations in the social (sociological, anthropological and behavioural) and medical (epidemiological, clinical and microbiological) domains need to be carried out over a short period of time. To complete the work successfully, there must be effective overall organisation and good co-ordination between members of the research team. Without this, work may be duplicated. This is inefficient and can also lead to annoyance on the part of individuals who may be approached by different members of the SASHI team without knowledge of previous approaches that have already been made to the same person. Lack of efficient management and co-ordination can also lead to interruption in data collection (if laboratory supplies or consumables for clinical examinations run out, for example) or to fieldworkers not being available during data collection opportunities. Data recording is also an area where failure of prompt and adequate documentation can lead to potentially irreversible losses of information.

In order to ensure efficient management and good co-ordination, clear lines of accountability need to be established. These should be agreed within the SASHI team during the training period. It is envisaged that there will be an overall SASHI co-ordinator and separate supervisors for the social science and medical components of SASHI. Together, these people will constitute the SASHI management team, augmented by any members of the Resource Group who are involved in the particular SASHI implementation. SASHI management team should meet formally to discuss SASHI progress once a week and should have informal communication between these meetings as necessary.

SASHI is designed as a multidisciplinary strategy and the social science and medical arms of SASHI need to be integrated in order to carry out some of the data collection steps. The need and rationale for this multidisciplinary approach are discussed in Chapters 1 and 2. In organisational terms, this multidisciplinary collaboration will involve a close working relationship between the social science and medical supervisors, reflected in regular meetings and joint review of SASHI progress. Supervisors should also ensure that field researchers working on each of their respective studies collaborate on the necessary steps (such as mapping and interviewing of private dermatovenereologists) and communicate on a regular basis throughout SASHI to learn from each others experiences. An example would be the social science field researchers obtaining information from the medical field researchers regarding the characteristics of STD patients they see, or conversely, the medical field researchers learning from the social science field researchers about the tactics used by persons who think they have an STD to obtain antibiotic medication prior to visiting a specialist. The responsibilities of the SASHI management team are outlined below and are given in more detail in Appendix 9.1.

SASHI Co-ordinator

Overall co-ordination of planning for SASHI (see chapter 3)

- ★ Obtaining necessary official permissions for implementing SASHI, providing official identification documents to researchers and liasing with senior officials as needed
- ★ Negotiating access to sites, institutions and individuals, where necessary, on behalf of researchers and facilitating a receptive and positive environment for implementation of SASHI
- ❖ Liaising with and arranging for inputs from Resource Group members in a timely manner
- ★ Recruiting medical and social science research supervisors
- ★ Arranging recruitment of medical and social science field researchers in collaboration with respective supervisors
- ★ Co-ordinating preparation of final SASHI report (by editing and contributing to report writing or by identifying other suitable persons to undertake this together with the research supervisors)
- ★ Ensuring thorough dissemination of the final report and SASHI findings to all contributors, stakeholders and potential users

Social science research supervisor

- ★ Recruiting field researchers (with Co-ordinator)
- ★ Training field researchers (with other SASHI management team members and resource persons)

- ★ Co-ordinating social science research team and social science data collection
- ★ Liaising and coordinating with medical research team
- ★ Supervising data collection (see Appendix 9.1 for procedures)
- ★ Monitoring data recording and initial coding of transcripts
- ★ Arranging and supervising social science data entry and translation of data where necessary
- ★ Analysing social science data
- ★ Preparing social science report and contributing to overall report writing

Medical research supervisor

- ★ Recruiting field researchers (with Co-ordinator)
- ★ Training fieldworkers (with other SASHI management team members and resource persons)
- ★ Liaising and co-ordinating with microbiology department and social research team
- ★ Supervising collection of medical data and activities of medical research team (see Appendix 9.1 for procedures)
- ★ Arranging quality control of laboratory tests
- ★ Ensuring data entry is carried out to a high standard
- ★ Analysing medical data
- ★ Writing medical report and contributing to overall report writing

Troubleshooting

Undertaking SASHI requires the supervision and management of a considerable body of work, undertaken by a fairly large team of researchers. It is inevitable that occasionally, unexpected problems will emerge. By their nature such unexpected events cannot be planned for. Therefore the SASHI management team should remain alert for warning signs of such potential problems. The quicker the response to emerging problems, the less disruption there will be to the smooth running of SASHI. It is important to act as soon as problems are identified and not wait until they become more serious and potentially unrecoverable errors may have occurred. It is also important to have backup contingencies planned in case of an unavoidable emergency, as, for example, occurred in one of the SASHI pilot sites when a malaria epidemic resulted in several members of the medical research team being posted to the outbreak area on emergency Government medical duty. In this instance some reorganization of the team members enabled the medical studies to continue, although sample collection was slowed down by this event.

In many cases, fieldworkers may be the first to become aware of the emergence of a problem. To benefit from this SASHI management team needs to maintain regular meetings with fieldworkers at which the development of problems can be discussed. There is a natural tendency for people to think that their supervisors do not want to hear of problems, will become annoyed or resort to accusations of incompetence by the fieldworkers. It is essential that this does not happen. Therefore, the SASHI management team must develop a supportive working relationship with fieldworkers, which encourages the raising of questions and the discussion on difficulties. At the weekly supervisory meeting, asking the fieldworkers about problems which have been encountered should, therefore, become a routine activity. The advice of appropriate Resource persons should be sought by the relevant supervisor and/or the Coordinator following discussion within the management team, if the problem is of a technical nature and is difficult to solve internally.

CHAPTER 10

Outcomes of SASHI

Introduction

This chapter describes the various potential uses of SASHI findings and the direct and indirect benefits that can result from carrying out SASHI in any given setting. It sets out the main outcomes of SASHI and discusses its adaptation for use in other country settings.

Short and long term uses of SASHI

The SASHI approach can generate data for immediate use as well as for use in the future, as discussed below. Certain additional outputs can also be obtained from SASHI that have been named 'spin-offs' in this section. The term 'stake holder' has been used here to indicate direct beneficiaries (also known as 'primary stakeholders') as well as indirect beneficiaries ('secondary stakeholders') who could be helped by using SASHI; this includes Government officers responsible for AIDS prevention and sexual health promotion projects (such as State AIDS Society officials), NGOs working in the field of sexual health, policy makers in Ministries of Health and Family Welfare, STD patients and people vulnerable to STD/HIV. Although the study has been piloted in India, during its development SASHI has taken into consideration the constraints that are often encountered in developing country situations. There is, therefore, the potential to use the SASHI approach in other developing countries, many of which are in neighbouring regions to India.

Immediate Utility

SASHI, with its social science and clinical epidemiology components, is able to generate a wealth of data on sexual health as applicable to a particular place and population. Depending upon the options chosen by the team carrying out situational analysis, a range of data on the following areas will be obtained:

- patterns and perceptions of sexual behaviour and their context
- treatment seeking behaviour of people related to sexual health and STDs/RTIs
- clinical and epidemiological profiles of STDs/RTIs
- potential partners for establishing programs aimed at improving sexual health

The data that are collected, after being appropriately analyzed and interpreted, can then be used for the following purposes:

- *reviewing existing programmes aimed at improving sexual health*
- *providing a baseline against which changes over time can be examined*
- *developing socio-culturally appropriate and cost-effective interventions*

Reviewing existing initiatives

A study using the SASHI approach in an area could come up with information that may encourage secondary stake holders or indirect beneficiaries of the study to think carefully about the adequacy and appropriateness of already existing interventions in the area with regard to sexual health. Modifications in on-going intervention programs may be made following the implementation of the SASHI approach and reviewing the results. For example, in one of the SASHI pilot sites there was a general notion among secondary stakeholders responsible for intervention programs that acute gonococcal urethritis had declined to almost zero in that area. The SASHI study findings showing the presence of N Gonorrhoea in both STD patients and general population offered a useful corrective, indicating that this notion needed to be revised and possible actions to control and prevent this infection are needed. This offers an example of this potential for the use of SASHI as a *useful alarm* to indicate where interventions are absent but may be needed.

Conversely, SASHI may provide information to suggest that existing initiatives are inappropriate or could have unforseen adverse effects. For example, sociological information collected during one of the SASHI pilot studies suggested that a health education initiative to provide information about sexual health and RTIs/STDs in a low-income area may have made some female residents more (rather than less) reluctant to seek treatment from local practitioners. This finding indicates a need to review this intervention and either withdraw or redesign it to make it more locally acceptable and hence more effective. It is just as important to ensure that existing preventative or control initiatives do not cause harm, or have negative effects, as to ensure that such initiatives are established. Besides indicating the kinds and foci of locally appropriate and cost-effective interventions that should be considered, SASHI can in some situations also be useful in indicating which interventions in particular areas or of particular types may not be locally advisable.

Providing a baseline for examining changes over time

As the SASHI approach (being a form of rapid assessment) collects data from a defined geographical area within a short time and in certain situations from a limited number of people, the resulting data may not be of the quality that is needed for long term prospective evaluation of an intervention program. For example, there may not be adequate representation of the whole population since a relatively small number of selected participants are involved. But the data obtained from SASHI activity could still

serve a useful role in terms of looking at broad trends in behaviours and in the epidemiology of STDs/RTIs. For example, in some towns in India HIV prevalence among STD clinic attenders increased from a very low level to a high proportion over only a few years. Repeating SASHI a few years after an initial assessment would allow identification of trends of this order. Similarly, reported increases in condom use could indicate changes in awareness and perhaps in behaviour over time from the situation when SASHI was initially conducted. Moreover, data collected from the large sample of the female general population (represented by antenatal clinic attenders) participating in SASHI could also contribute effectively to the national sentinel surveillance data base.

Developing socio-culturally appropriate and cost-effective interventions

Without a firm political commitment for subsequent development of appropriate interventions to prevent STD/HIV on the part of the SASHI study implementors and other key stakeholders, no situational analysis should be undertaken as it would be a waste of resources to undertake such an analysis without any intention to act on the findings. An approach that could help in developing effective interventions subsequently is by addressing the felt needs of stake holders at the initial stage of planning and preparation of SASHI and choosing between the options described in Chapter 2 based on these felt needs. Making skilled manpower and funds available and ensuring comprehensive analysis of the data from both of the components (social science and medical) would also play an important role in contributing to the development of effective intervention tools.

SASHI findings may indicate the need for certain interventions that can quite rapidly be undertaken, as well as for ones that might require further more focused work to design and implement. Interventions may take the form of administrative, legislative, structural or environmental measures and need not only be medical or educational in nature. As suggested in the previous section however, SASHI can also provide information that may suggest that certain kinds of interventions are inappropriate. Improperly planned and designed interventions can easily do more harm than good and SASHI might come up with information that contradicts local assumptions and would be appropriately used to reconsider the value of initiatives that might otherwise have been put into place given inadequate knowledge of the local situation.

Potential spin-offs

There are several potential spin-offs, or indirect benefits, that come out of SASHI apart from the information that is gathered on the local situation and these are described here.

1. Empowerment and capacity building at the local level. Both those carrying out SASHI and the participants or informants and potential beneficiaries of subsequent interventions may be empowered as a result of involvement with SASHI. With regard to the SASHI team members, the social science researchers who study

different aspects of behaviours and practices related to sexual health will become more confident through their growing ability to make contact with and understand the circumstances of members of vulnerable and 'hard to access' populations. Also contact with vulnerable populations often changes attitudes significantly among members of the research team who have previously had little or no communication with communities other than their own and helps to break down prejudices and misperceptions on all sides. This developing expertise among social science researchers has immense value by virtue of being specific for local trouble shooting and the same workforce could be utilized for facilitating or evaluating interventions designed for those populations in need. Medical researchers will also gain valuable experience in designing and analysing epidemiological studies and in carrying out clinical investigations for research purposes, which will enhance capacity for the future. They will also gain important insights into their patients' lives and into the nature of medical services which will increase their ability to make appropriate and informed professional judgements. In addition, the quality control exercise introduced in the laboratory conducting SASHI investigations will enhance local microbiological capacity to conduct future scientific studies. Local informants or potential beneficiaries may also gain confidence in their ability to represent their communities and to articulate their problems and needs to concerned persons by participating in SASHI, and this may lay the foundation for participatory intervention activities (see point 3 below).

2. Networking naturally occurs between different local institutions and individuals and between local and other regional facilities and resource persons during the implementation of SASHI. This will help in conducting any further studies that may be needed in the future through sharing of expertise and will also help to encourage collaboration in the development and implementation of interventions in different sites. Details of potential local collaborators, partners and institutions for developing sexual health projects locally will also have been produced as part of SASHI and the relevant appendix of the site report will provide a useful reference for planners when beginning to prepare for intervention activities.

3. With respect to the potential beneficiaries of initiatives aimed at promoting sexual health and reducting the risk of HIV infection, the process of making contact with members of these communities and seeking their knowledge and assistance in data collection inevitably occurs as part of SASHI activities. This process can in itself be an important first step towards building initial links into such populations to provide a basis for consultation with these potential beneficiaries; their subsequent active participation in the development and implementation of interventions is essential for the success of any such intervention. For this reason it is particularly important for the data collection activities carried out during SASHI and the researchers involved in these to be closely connected, wherever possible, with the initiation of subsequent steps to develop interventions.

Carrying SASHI forward: Future uses and new settings

In addition to providing a methodological strategy and data collection protocol for carrying out a situational analysis in any chosen setting, SASHI has a further potential benefit for the development of initiatives to prevent HIV and improve sexual health in a region more generally. Because it provides a standardised approach to collecting data on sexual health and sexual behaviour, the knowledge gained from SASHI will be cumulative over time. As SASHI is conducted in successive sites, the information gathered can be pooled and compared systematically in order to build up a more comprehensive picture and determine what general trends emerge. This is extremely important as it will provide a means to inform the development of interventions and control strategies in the many sites where it will not be possible to conduct a situational analysis. Therefore it is essential to share findings from SASHI both with other SASHI sites and with other organizations and authorities wishing to develop sexual health-related interventions in other settings of the region.

Further afield, adequate knowledge of the local situation is lacking in many developing countries. In many settings beyond as well as within India there is a perceived need for a tool like SASHI through which information that is necessary for decision-making and prioritization regarding interventions for sexual health can be collected. Although SASHI was designed specifically for use within the Indian context, the methodological approaches that are used and the range of data collection strategies are potentially implementable anywhere, if appropriately adapted to the specific features of different health systems, social contexts and organizational settings where these would affect the proposed approaches to data collection. If potential users intend to ustilise this package in a setting outside India, they are advised to pay careful attention to the need to adapt not only recommended settings for collection of data but also the specific data collection guides for each step and stage, which will need to be modified and revised in order to be made suitable for a different socio-cultural context. Advice may be sought from members of the original Central Resource Group which designed the SASHI protocol.

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In both of the pilot sites we wish to express our gratitude not only to the local researchers themselves but to the many public and private health care institutions and individual medical practitioners, and to the government officers and staff of non-governmental organisations, who assisted them and provided information. We particularly wish to thank the managers and workers of the two organisations which agreed to participate in the male general population study and took a genuine interest in the study and its findings but which, for reasons of confidentially, must remain anonymous. We also owe a special debt of gratitude to the numerous individuals who spared time to participate in the pilot studies and shared valuable and often sensitive information with the researchers.

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Helen Lambert (for the SASHI Central Resource Team)
June 2000

APPENDIX 2.1

BASIC, INTERMEDIATE AND ADVANCED LABORATORY TESTS FOR SASHI
(Tests Used in Minimum, Standard And Comprehensive Sashi Options respectively)

STD	TEST	COMMENTS
BASIC		
1. Syphilis	VDRL TPHA	Simple, low cost, available at all labs Simple, locally available
2. N. Gonorrhoea infection	Gram stain	Simple, easily available
3. Trichomonal vaginosis	Wet preparation	Simple, low cost, available and reliable
4. Candidial vaginosis	Gram stain	Simple, low cost, available and reliable
5. Bacterial vaginosis	Gram stain	Easy to perform. Training needed for interpretation of gram stain
INTERMEDIATE		
1. HIV infection* (*if desired by SAC/SAS)	HIV 1&2 antibody ELISA	SAS could make it available or may be purchased
2. Chlamydial infection	·Chlamydia antigen detection ELISA ·Chlamydia blocking test	Locally available and costly, but cost may be met through SASHI funding
3. Herpes simplex infection	Herpes simplex antigen detection ELISA	Locally available and costly, but cost may be met through SASHI funding
4. Gonorrhoea	Culture and drug sensitivity test	Locally available. Requires skills and expertise of microbiologist. Organisms are fastidious and difficult to grow

STD	TEST	COMMENTS
ADVANCED		
1. PCR for gonorrhoea	PCR test	Not locally available, very costly. Technical expertise & facilities available at national /specialist centres and reference laboratories only
2. PCR for chlamydia	PCR test	Not locally available, very costly. Technical expertise & facilities available at national /specialist centres and reference laboratories only
3. Urine Test	Urine dipsticks for albumin and sugar	Locally available

APPENDIX 3.1

PERSONNEL REQUIREMENTS

3.1 Personnel Requirements

Organization and membership of SASHI team

SASHI is undertaken by two sub-teams of researchers : a 'social science' team, which is responsible for collecting most of the social science - sociological, anthropological and behavioural - data, and a 'medical' team, which is responsible for collecting most of the clinical, epidemiological and microbiological data. One Project coordinator will oversee the work of both the teams and be responsible for all administrative and organizational liason and arrangements for SASHI overall, while two Supervisors, one each for the social science and medical teams, will supervise the work of these two teams respectively.

The designation of each type of team member and their desired qualifications and background are given below in Table 1. Obviously, it will not always be possible to recruit persons with all of the background characteristics listed in this Table and in some cases personal qualities may be more important than formal qualifications. For example, in the case of the social science field researchers, the ability and willingness to meet and interact with people from a wide range of backgrounds including those in very deprived and marginal circumstances, a lack of undue concern for social propriety which might constrain their movements, and a mature and sympathetic attitude, are more important than formal qualifications.

Table 1 describes the SASHI personnel who will need to be recruited to work on the SASHI study on a full or part-time basis. Full-time is always preferable but part-time may be necessary in the case, for example, of practising doctors who may need to continue some of their duties in a hospital setting, or for academic faculty who need to continue some of their teaching and administrative duties while supervising SASHI. Where no adequately experienced and qualified person can be recruited as a full-time Supervisor for one of the teams, it may be possible to have a pair of part-time Supervisors instead. In the SASHI pilots, for example, no sufficiently qualified and experienced social scientist was available to work full time on SASHI. However, it was possible to recruit an University academic on a part-time basis, together with a social scientist who was based in the medical department where SASHI was housed. The University academic was more experienced in conducting research; the social worker had a postgraduate degree in social science and much familiarity with medical counselling and STD patients, but little experience of doing research. The University academic provided essential overall guidance in terms of research direction, review and analysis of findings and ongoing supervision of research techniques, while the hospital-based social scientist managed the field research team on a daily basis, monitored the data collection process and guided the weekly team meetings. The two co-supervisors

jointly reviewed the overall directions and priorities for the data collection as the pilot proceeded and collaborated in data analysis and report writing. Hence where arrangements for complementary working can be made, joint Supervision can work well and this is preferable to a situation where a Supervisor with insufficient skills and capacity is expected to manage the work alone.

The minimum essential staff requirements are given in Table 1, but according to the level of laboratory facilities being used and the complexity of the tests being done (see Table F1 in Section F) the staffing pattern for the laboratory elements of the medical team will vary greatly. Therefore, the staffing requirements for the laboratory components of SASHI are set out separately in Table 2. The SASHI team as a whole will require advisory and consultative input at key stages from a resource group of technical experts, described in the next section.

Table 1: Overall staffing requirements for all components of SASHI

Designation	Number of persons needed	Appropriate background
Project Co-ordinator	1	A fairly senior person with established local credibility, some experience of research work and supervising research staff, familiarity with local official hierarchies and with the health field; preferably some knowledge of sexual/ reproductive health (e.g. Head of a medical dept. or of an established NGO working in the health field)
Secretary / Data-entry Operator	1 (2)	Preferably secondary school leaver. Good typing skills, knowledge of word processing, some experience of data base programmes or ability to learn a basic software package for quantitative data entry, preferably some experience of data management. A second person would enable double entry of quantitative data if resources allow.

Designation	Number of persons needed	Appropriate background
Social Science Team		
Social Science Supervisor	1	Senior person having familiarity with qualitative research methods, some experience of health-related work and/ or postgraduate qualification in relevant social science such as social work, sociology, psychology or social anthropology, experience of supervising teams, moderate fluency in English, some experience of community-based research or other work, non-judgemental attitude (e.g. Senior Faculty of a university dept, experienced NGO staff member such as a social worker or counsellor).
Social Science Field Researcher	6 (equal numbers of males and females)	Postgraduate qualification preferably in a social science, command of English, mature approach, non-judgemental attitude, some experience of research work and/or community-based work, some knowledge of qualitative methods
Medical Team		
Medical Supervisor	1	Senior person with MBBS and preferably postgraduate qualification (probably DPH/MD and if possible in epidemiology, though this is rarely available), some experience of research projects and of team management
Medical Researcher	4 - 6	Experienced postgraduate physicians, who are presently specialising in dermato-venereology (2 - 4) and obstetrics and gynaecology (2); ability to understand the need for rigorous consent-taking procedures and capacity to grasp basics of clinical epidemiology

Designation	Number of persons needed	Appropriate background
Microbiologist	1	Senior qualified person with experience in both microbiology and serology. Familiarity with and ability to conduct and supervise the tests listed in Table F1; preferably having experience in performing culture and sensitivity testing of gonococci.
Laboratory Technician	2	Experience in microscopy of trichomoniasis and preferably in bacteriology covering the tests listed in Table F1 (1); experience in serology (see table F1(1))
Peon/Laboratory Assistant	1	No special background needed, but energetic and bright, with good knowledge of the local site and depts. involved, and good interpersonal skills
Statistician or Epidemiologist	1 (either part-time or provided through an external consultant)	Experience in data base programmes preferably including EpiInfo, Excel or dBase, to supervise data entry, management and analysis and provide training to secretary/data entry clerk(s).

Table 2: Staffing pattern for SASHI with basic, intermediate and advanced laboratory facilities.

(a) Basic Lab Facilities

Designation	Qualifications	Duties
(1) Prof. & Head of the Microbiology department	MD (Patho & Micro)/ MD (Microbiology)/ Ph.D (Microbiology)	1. Supervision, provision of space and other facilities Or Assoc. Prof./Senior lecturer/ Microbiologist in charge of lab 2. Set up the process of reception and processing of samples 3. Reading of test results 4. Interpretation of results 5. Correlation with clinical findings 6. Quality control. 7. Any other work related to SASHI project.
(2) Laboratory Technician	Ph D (Microbiology)/ M.Sc. (Microbiology)/ B.Sc. (Microbiology)/ B.Sc. (D.M.L.T.)	1. Preparation of sample collection trays 2. Help in collection of samples 3. Carry out lab tests for STDs 4. Quality control 5. Test recording & tabulation of results 6. Any other work related to SASHI project
(3) Laboratory Assistant/Peon	8/9 standard or above	1. Work related to project & ordered by Microbiologist & lab technician 2. Any other work related to SASHI project

(b) Intermediate Lab Facilities

In addition to the staff for basic lab facilities:

Designation	Qualifications	Duties
(4) Research Assistant	PhD (Microbiology)/ MSc (Microbiology)/ BSc & DMLT Experience in ELISA	1.Carry out ELISA tests for STDs & help other technician in record keeping & lab work 2.Any other work related to SASHI project

(c) Advanced Lab Facilities

In addition to the staff for both basic and intermediate facilities:

Designation	Qualifications	Duties
(5) Senior Scientific Officer	PhD (Microbiology)/ PhD (Molecular biology) Experience in PCR	1. Carry out PCR on STDs 2. Any other work related to SASHI project
(6) Laboratory Technician	MSc (Microbiology)/ BSc & DMLT	1. Help SSO in PCR 2. Any other work related to SASHI project

Advisory Expertise - the SASHI Resource Group

In addition to the individuals specified in the previous section and Table 1, it is essential that the agencies implementing SASHI, the Coordinator and the SASHI research team have access to technical experts, who are familiar with the SASHI approach and with multidisciplinary work on sexual health.

In general terms, these people must be familiar with the SASHI approach and with the rationale for the use of rapid assessment procedures, as well as with multidisciplinary approaches to research in health. In addition they will need to have technical expertise covering the following areas:

- Microbiological studies of STDs & RTIs
- Epidemiological research design and data analysis, Clinical epidemiology of STDs, RTIs and HIV
- Qualitative research methods as applied to health (participant observation, in-depth interviews, group discussions)
- Community- or field-based social research
- Anthropological or sociological research design and qualitative data analysis
- Research on sensitive issues such as sexual health
- Familiarity with current interventions to prevent HIV transmission and promote sexual health
- Training and supervision of new researchers in data collection methods and techniques of data analysis and interpretation
- Knowledge of policy issues concerning sexual health and HIV prevention

Where local persons or individuals based in the same geographical regions have expertise in the relevant areas, the Coordinator should consider recruiting them as advisers. Those without skills and experience in the relevant areas should not, however, be expected to substitute for those who have such experience. Over time it should be possible to build up Resource Groups of persons for different geographical regions who have acquired experience in implementing SASHI from previous involvement in SASHI projects.

During the piloting of SASHI, the group of resource persons that designed and facilitated the pilot implementation of SASHI and then developed the current package was designated the 'Central Resource Team'. It had the following membership, together with some additional inputs from other individuals at particular stages of the work:

Name	Main Discipline	Affiliation
Dr. Shalini Bharat	Psychology	Tata Institute of Social Sciences, Mumbai
Dr. Geeta Bhave	Microbiology	KEM Hospital, Mumbai
Prof. George Davey Smith	Epidemiology	Department of Social Medicine, Bristol University, UK
Dr. Heiner Grosskurth	STD epidemiology	London School of Hygiene and and Tropical Medicine, UK
Dr. Surinder Jaswal	Medical social work	Tata Institute of Social Sciences, Mumbai
Dr. Helen Lambert (Team Leader)	Medical anthropology	London School of Hygiene and Tropical Medicine, UK
Dr. Samiran Panda	Clinical epidemiology	Project RIICE, Society for Applied Studies, Calcutta

(Various members of this team, together with additional resource persons who they are training, will be involved in the future implementation of SASHI in new sites if desired.) NACO and DFIDI we currently deiaring the establishment of a central contact part of SASHI in India. In the meantime queries may he odrened either to NACO of the Health Advisory Group, DFID India.

APPENDIX 3.2

INSTITUTIONAL AND OFFICE REQUIREMENTS

3.2: Institutional and office requirements

Project Office

SASHI should be housed within an institution that can provide sufficient designated project office space for the researchers in both teams to gather for weekly team meetings, for writing up field notes (in the case of the social science researchers) and for storing data, data recording and collection forms, laboratory supplies when they are delivered and other equipment. Since clinical facilities are required for the medical component of SASHI, this institution is likely to be a public hospital or medical college but if SASHI is to be based within such a health facility, the coordinator must ensure that the social science as well as the medical members of the SASHI team have free access to all the facilities designated for SASHI. Alternatively SASHI could be housed, for example, within a non-governmental organization or an institute of higher education such as a University department or college and the same access requirements will apply to all members of the team. Specific equipment and space requirements are as follows:

- At least one room of sufficient size and with adequate furniture to allow 12-15 people to hold meetings
- Several tables or desks for writing and an adequate number of chairs
- At least one, preferably two, lockable cupboards with free shelves for storing both blank and completed data sheets
- A desktop computer, installed with MS Windows, Word for Windows (or other word processing programme) and EPI-INFO, and a printer, kept in a lockable room
- A photocopier or easy access to photocopying facilities
- A telephone
- A fax or easy access to fax facilities

Other institutional facilities

Wherever the project office is located, SASHI will require collaboration with and utilization of an adequately equipped laboratory with sufficient freezer space for

samples to be kept and storage space to store other laboratory supplies for use during SASHI. Laboratory equipment that is already available in the institution which is carrying out SASHI should be thoroughly checked for proper functioning during the training period and necessary repairs completed immediately under the supervision of the SASHI medical supervisor. The laboratory facilities required to undertake ELISA testing are as follows:

(1) ELISA Reader and Washing system, Auto pipettes etc.

(2) A counter space for carrying out tests

(3) Table and chair space for working & recording results

(4) A cupboard with lock and key

(5) A refrigerator space with lock & key

(6) Deep freezer (- 20°C or lower)

In addition, for the medical components of data collection, access will be required to dermato-venereological and gynaecological outpatients clinics and to a busy antenatal clinic. Where (as is likely, at least for the former two types of clinic) government facilities are mainly being used, access will also be needed to some private clinical facilities in order to obtain a subsample of patients (see Stage E of the protocol in Chapter 5). To facilitate the collection of specimens there should be sufficient space at each of these clinics in the examination area to place a tray containing the necessary equipment.

APPENDIX 3.3

LABORATORY SUPPLIES AND EQUIPMENT

Table 3.31 Kits, Reagents, Equipment for Laboratory Tests

Lab Test	Reagents Kits	Equipment
1. VDRL	VDRL card test kit or VDRL kit	VDRL shaker
2. TPHA	TPHA kit	Nil
3. HIV 1&2 antibody ELISA	HIV 1&2 antibody ELISA kit	ELISA washing system and reader
4. Chlamydia antigen test Chlamydia blocking test	Chlamydia antigen ELISA kit	ELISA washing system and reader
5. Herpes simplex antigen test	Herpes simplex antigen ELISA kit	ELISA washing system and reader
6. Wet preparation for trichomas	Slide, cover slip and saline	Microscope
7. Gram stain for candida	Gram stain	Microscope
8. Gram stain for bacterial vaginosis	Gram stain	Microscope
9. N. gonorrhoea smear and culture and drug sensitivity	· Gram stain · Theyer-Martin medium · E test	Candle jar Incubator Microscope
10. Urine albumin and sugar test	Urine dipsticks for albumin and sugar	None
11. N. gonorrhoea PCR	PCR kit	Thermal cycler
12. Chlamydia - PCR	PCR kit	Thermal cycler

3.32 General Laboratory Equipment Required

1. Refrigerator
2. Centrifuge
3. Incubator
4. Microscope
5. Cyclomixer
6. Deep freezer (-20°C or lower)

3.33 General Laboratory Supplies Required

1. Pipette Tip Yellow, 1-200ml
2. Micro Glass Slides
3. Micro Cover Glasses
4. Plain Tubes 10ml
5. Needles 22G x 1.5"
6. Holder
7. Full Autoclavable Digital Micro Pipette with Built in Tip Ejector and Locking Mechanism: 20ml to 200ml
8. Rection Tubes 1.5ml with Skirt Screw Version together with Caps with O-Ring
9. Pasteur Pipette
10. Self Standing Screw Cap Tubes with "O" Ring
11. Test Tube Holder
12. Savlon
13. Trays
14. Sterile Water for Injection
15. Speculum
16. Gloves
17. Spirit Lamp
18. Tornicate Belt
19. Methanol
20. Cover Slips
21. Diamond Pencil
22. Forceps
23. Boxes for Storing Slides
24. Bleaching Powder
25. Xylene
26. DPX Mountant
27. Filter Paper Ordinary/Whatman No.1
28. Slide Box
29. Labels
30. Thermometer -20°C
31. 2ml Cryo Vials with Screw Cap in assorted colours, Sterile [PCR]
32. Urine Containers 70ml [PCR]
33. Plastic Droppers [PCR]
34. Cryo Vial Containers with Thermocol Packing [PCR]
35. EIA Chlamydia Blocking Reagent (40 tests) [Chlamydia]
36. EIA Chlamydia (96 tests wells) [Chlamydia]
37. Urine Dip Stick Tests [Urine Sugar]
38. 200 Tests TPHA kit [Syphilis]
39. 94 x 16mm Petridish with Lid [N. Gonorrhoea Culture]
40. 145 x 20mm Petridish [N. Gonorrhoea Drug Resistance]
41. Candle jars [N. Gonorrhoea]

APPENDIX 5.1

DATA COLLECTION GUIDES AND DATA RECORDING FORMS

Data Collection Guide for B1: Interviews with Officials

Record background information on informant's name, occupation and official designation.

Describe SASHI and its purpose and broadly describe the data collection activities involved.

Ask for assistance from the official and from the agencies and individuals under his/her authority, including provision, where necessary, of letters of introduction or other help in facilitating access to particular subordinate officers.

Record any information that the interviewee provides in general in response to hearing about SASHI, including any observations that they can make on the following:

High risk situations and behaviours in the area, including most and least desirable areas of the SASHI site, locations of and information about people involved in legal and illegal alcohol consumption, illicit drug taking, prostitution, locations where migrant workers and out-of-town visitors (drivers, tourists, salesmen) live or stay and any significant changes in these locations and populations in the last 5 years, information about marginalised or minority groups other than those mostly talked about such as CSWs, migrant workers etc.

Ask for and record specific names and contact details of useful informants who may be knowledgeable about the above topics and request the official to make arrangements for access to these informants and to other potentially knowledgeable persons who are under the interviewee's authority, if this can be organized by him/her. For example police chiefs should be asked to provide permission to approach individual officers who are posted at particular police stations covering relevant localities. Similarly municipal commissioners should be asked for permission to approach subordinate officials who will have knowledge of relevant localities in their area of jurisdiction.

CODE NO: ☐☐☐☐☐☐

Data recording form for B1: Interviews with officials

DATE: INTERVIEWEE:

LOCATION: INTERVIEWER:

Occupation:

Official title:

Sex:

Data Collection Guide for B2: Interviews with key informants

Record background information on informant including:

- *name*
- *address or area of business/residence (as appropriate)*
- *sex*
- *estimated age*
- *occupation (official designation if relevant and actual nature of work)*
- *estimate of socio-economic status*

Describe SASHI and its purpose and the data collection activities involved.

For key informants who are officials, record information on:

a) high risk situations and behaviours in the area

Record information about most and least desirable areas of the site, locations of legal and illegal alcohol consumption, illicit drug taking, prostitution, locations where migrant workers and out-of-town visitors (drivers, salesmen) live and visit and any significant changes in these locations and populations in the last 5 years, vulnerable groups etc. .

b) local organizations and social resources

Record information about local NGOs, religious societies and others providing legal, health, social welfare, housing, rehabilitation or other services, the populations they serve, the nature of their work and contact details (including if possible a named individual in each organization)

c) further informants and contacts

Record names and contact details of further useful informants particularly on topic a); arrangements for access to these informants and to other potentially knowledgeable persons within this interviewee's workplace or residential area if they can organize this.

For key informants from shops or business establishments, record:

- *Where they work, nature of work*
- *how long they have worked there*
- *information about the establishment (if a shop, restaurant, hotel etc.) and how many people work there*
- *information about users: how many people use the facility if shop, restaurant etc, where such people are from and what sort of clientele at different times and seasons*

For community-based key informants (e.g. local residents, community leaders) record:

- *information about the local community including where local people go for health care, for what kind of health problems.*
- *local leisure activities, of men and of women*
- *locations and times of high risk behaviour, main participants, nature of risk behaviour*
- *further useful contacts/informants.*

CODE NO: ☐☐☐☐☐☐

Data recording form for B2: Interviews with key informants

DATE: INTERVIEWEE:

LOCATION: INTERVIEWER:

Address:

Sex: *Age:* *Marital Status:*

Occupation:

Estimated socio-economic status:

Data Collection Guide for B3: Mapping sites and locations

Record background information on location and time period of observation.

Record general observations on the nature of the site and significant features including:

- *types of houses and other structures (kacca, pucca, semi-pucca)*
- *state of upkeep of buildings in area*
- *general appearance of site, location of parks, lanes etc.*
- *numbers, types and geographical positions of shops, businesses, vendors, health facilities, eating places, cinema houses, sheds, urinals (make a sketch map)*

Record specific observations on activities at the site during observation period including:

- *level of activity (how crowded, numbers of people overall)*
- *types of person at the site (ages, sex, social class)*
- *what types of activity these persons are engaged in - which are passing through, which are spending time at the site and doing what*
- *nature and locations of interactions at the site*
- *number of interactions by different categories of person*
- *numbers and characteristics of individuals observed engaging in interactions likely to relate to high risk sexual behaviour (e.g. male or female sex workers and potential clients)*
- *any other notable observations, including verbal exchanges if audible and relevant*

CODE NO: ☐☐☐☐☐☐

Data recording form for B3: Mapping sites and locations

DATE: OBSERVER:

LOCATION: TIME PERIOD:

CODE NO: ☐☐☐☐☐☐

Data recording form for B4: Mapping facilities for STD treatment

Name of facility (if different from practitioner, e.g.'Holy Cross Clinic', Medical College Skin')	**Name of practitioner** (if displayed; for facilities with several practitioners, record all names)	**Medical tradition** (descriptive, e.g. allopathy; electromagnetism; religious *(ojha); siddha; unani; homeopathy)*	**Specialisation & qualifications** (e.g. dermato-venereology, MBBS, MD; B.A.M.S.; B.E.M.S.; pandit; pharmacist)	**Full address & contact details** (include name of neighbourhood or locality/area in urban sites and telephone number where available)

Data Collection Guide for C1: Participant observation with hard to access populations & places

*Dress informally in a way that is appropriate for the setting of the participant observation. Refer to the other data collection guides for steps in this stage (**C**) for guidance on the kinds of topics of enquiry, as appropriate. Good strategies for participant observation are:*

- *visiting the location where you want to collect information at frequent, regular intervals (e.g. at the same time each day) and taking tea or pan from the same stall or sitting in the same place for some time; then once your presence has become familiar, gradually establishing conversation with the shop owner, other customers, bystanders (this may be appropriate for example in public places which are known as locations where men go to pick up other men, or women, for sex, or in a residential area where known prostitutes work)*

- *visiting the location in the guise of a potential male customer or contact, for example by hiring a room in a lodge where commercial sex work is said to take place in order to observe and gather information informally from room boys and others, or by loitering in a place where men who have sex with men are known to meet in order to observe and engage in conversation with such men (this may be appropriate where open access is not possible or local people are particularly suspicious)*

If you do not want to be identified as a researcher, think of an appropriate introduction and stick to it. Otherwise do not volunteer this information, but do not lie if asked. In some settings useful information may be obtained by saying that you are a visitor, or are new to the area, and want to learn more about the place. Subsequent questioning should be done unobtrusively in the course of conversation but if informants turn out to be helpful and cooperative, similar topics should be covered as indicated in the data collection guides for subsequent steps of stages C and D (as appropriate according to the setting and informant). Do not take notes while in the field. Write up notes immediately after, rather than during, the participant observation period, including exact details of words used if any conversation occurs or is overhead that is relevant to the study.

N.B. Data recording form for C1 should be used only to report observations, descriptions of scenes, dialogue and interactions not classifiable under other steps. Where participant observation results in detailed information being gathered from particular informants or topics covered in other topic guides, use data recording forms C4, C5 (i), C5(ii) or C5 (iii) (or if groups of informants of the appropriate types, C2 or C3), as appropriate. Also refer to the associated data collection guides for relevant questions and areas of enquiry.

CODE NO: ☐☐☐☐☐☐

Data recording form for C1: Participant observation

N.B. Use form only for data NOT classifiable under C3, C4, C5 (i), C5 (ii) or C5 (iii).

DATE: INFORMANT(S):

LOCATION: RESEARCHER:

Approximate Age(s): *Marital status(es) if known:*

Occupation(s):

Estimated educational level(s): *Estimate of socio-economic status(es):*

Additional exercise: If this is the first contact with the residential community identified as one where HRB may be occurring, first carry out a 'Social Mapping' exercise. If conducted on the ground using non-transferable materials,such as sticks and pebbles, reproduce the map on the data recording form.

Record background information on participants:

- *Age range*
- *Occupations*
- *Marital status*
- *Estimate of socioeconomic status*
- *Educational level*

Record information about:

a) *characteristics of the area and people living there, region to which they belong.*
b) *occupational and leisure activities of different groups of people in the community.*
c) *main concerns and problems among women in this community (ask them to list all problems)*
d) *main health problems among women (ask them to list all that they can think of); and perceptions of and local terms for reproductive/sexual health problems in particular. If sexually related problems are not initially mentioned in the list, ask: 'What are the general sexual problems or concerns that people in this community face?' If they are mentioned ask if there are any other similar or related problems. Then probe on the following points:*

- *what are the local names for these conditions*
- *how are they recognised (symptoms and signs), descriptions of problems experienced*
- *which are thought to be sexually transmitted and which are not*
- *any other illnesses associated with sex*

e) *treatment-seeking practices:*

- *what do people do when they have such a problem (where do they go, about self-treatment and its nature), any obstacles to seeking treatment*
- *who do they talk to, who do they get advice from (if anyone)*

f) *high risk behaviours and perceptions of risk and prevention:*

- *who gets or is likely to get these kinds of conditions (age groups, sex, income level and occupation) and why*
- *where and how are they likely to get them (probe on behaviour of local men as well as women)*
- *local opinions of those at risk of getting these conditions (what is thought about them, labels used for them)*
- *how can people avoid acquiring these conditions; any obstacles to avoiding these conditions*

CODE NO: ☐☐☐☐☐☐

Data recording form for C2: Community-based group discussions with women

DATE: INTERVIEWEES:

LOCATION: INTERVIEWER:

Age range: *Marital status:*

Occupations:

Educational level: *Estimate of socio-economic status:*

Individuals identified for case history follow up:

Data Collection Guide for C3: Group discussions with men at high risk

Additional exercise: When carried out in a locality or workplace-related site identified as one where HRB may be occurring and where this step is the first contact with the community, first carry out a 'Social Mapping' exercise. If produced using non-transferable materials, reproduce the map on the data recording form.

Record background information on:

- *Age range*
- *Occupation*
- *Marital status*
- *Educational level*
- *Estimated socio-economic status*

Record information about:

a) *characteristics of the site and people living there*

b) *occupational and leisure activities - where men go when not working or at home*

c) *main problems and concerns faced by men working in this occupation*

d) *common health problems among men (ask them to list all they can think of)*

e) *perceptions of and local terms for reproductive/sexual health problems in men: If not mentioned initially in general listing, ask, 'What are the general sexual problems or concerns that men in the community face?' and probe on the following points:*

- *what are the local names for these conditions*
- *how are they recognised (symptoms and signs)*
- *which are thought to be sexually transmitted and which are not*
- *any other health complaints associated with sex*

f) *treatment-seeking practices:*

- *what do people do when they have such a problem (where do they go, also self-treatment and its nature), any obstacles to obtaining treatment*
- *who do they talk to, who do they get advice from*

g) *high risk behaviours and perceptions of risk and prevention:*

- *who gets these kinds of conditions in this place (probe on characteristics of those at risk locally and behvaviours involved) and why*
- *where and how are they likely to get them (probe on behaviour of local men and women)*
- *local opinions of those at risk*
- *how can people avoid getting these conditions; any obstacles to prevention*

CODE NO: ☐☐☐☐☐☐

Data recording form for C3: Group discussions with men at high risk

DATE:

INTERVIEWEES:

LOCATION:

INTERVIEWER:

Age range:

Marital status:

Occupation:

Educational level:

Estimated socio-economic status:

Individuals identified for case history follow up:

Record background information on:

- *Address*
- *Age*
- *Marital Status*
- *Occupation*
- *Educational level*
- *Estimated socio-economic status*

Record information on:

a) *what is the problem (record in the respondent's own words)*

b) *when did the interviewee first become aware of the problem, also if it has occurred before*

c) *nature of the problem (symptoms and signs)*

d) *advice sought, if any, and from whom (especially if it is for the first time)*

e) *perception of the cause(s) - whether sexually transmitted - both when the problem first arose and now*

f) *treatment-seeking history, including:*

- *self-medication*
- *treatment providers and how identified*
- *details of treatment given and effects*
- *information and advice received about the problem from treatment providers*
- *rough time sequence of each type of medication*
- *cost of medication*

g) *is this a common problem among people in his/her community/social circle*

h) *whether/how this condition can be prevented*

i) *any other names given to this condition; any other similar health problems they are aware of*

j) *what happens if this condition is not treated successfully; if similar diseases are not treated*

CODE NO: ☐☐☐☐☐☐

Data recording form for C4: Collection of case histories (community-based)

DATE: INTERVIEWEE:

LOCATION: INTERVIEWER:

Address:

Age: *Marital Status:*

Occupation:

Educational level: *Estimated socio-economic status:*

Data Collection Guide for C5 (i): Interviews with female sex workers

Record background information on:

- *Location (place) of work and (general area) of residence*
- *Age*
- *Marital status*
- *Ages and sexes of children, if any*
- *Educational level*
- *Estimated socio-economic status*

Record information on:

a) *how long interviewee has been working in present place*
b) *where from, if not native of site (collect brief occupational history if appropriate)*
c) *circumstances of entering this profession*
d) *main problems and concerns experienced by interviewee (personal and occupational)*
e) *occupation-related networks (involvement of autodrivers, pimps, police, etc.)*
f) *nature of relationships with other sex workers (friends/competitors/mutual assistance)*
g) *other characteristics of trade locally (how organized, other locations, others involved)*
h) *what kinds of clients come - ages, occupations, places of residence, marital status*
i) *how many clients came yesterday; how many come on average daily*
j) *proportion of regular and new clientele - how often do regulars come*
k) *what kinds of requirements do clients have, including*

- *types of sex*
- *how long clients spend with informant usually*
- *whether they eat/drink alcohol during visit, whether they go out together etc.*
- *frequency of violence and force*

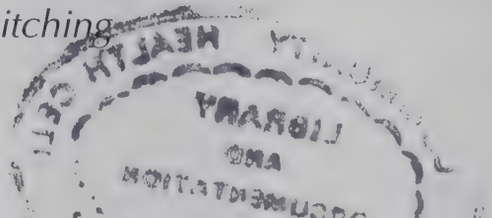
l) *details of payment, including*

- *how much is charged for each type of service*
- *how much of the payment is then given to others e.g. madams or pimps and to whom*

m) *details of condom use, including*

- *what proportion of clients use condoms*
- *whether sex worker or client asks for them to be used and whether provided by client*
- *if provided by sex worker, where are they obtained*
- *any obstacles to condom use, what problems in condom use*

n) *do any health problems arise from this work - if not mentioned, ask about back pain, lower abdominal pain, vaginal discharge, itching*



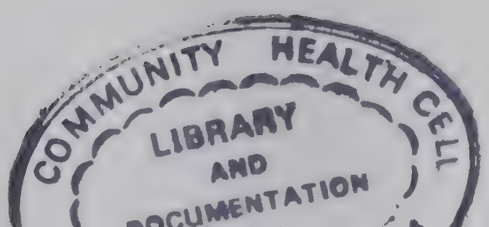
o) *details of last such health problem that interviewee had, including*

- *nature of problem and details of symptoms*
- *what was done including treatment-seeking*
- *from where advice and treatment were obtained*
- *costs incurred and results*

p) *perceptions of cause, risk and prevention*

- *which diseases are sexually transmitted*
- *which are not sexually transmitted*
- *any other health problems associated with sex*
- *how can they be avoided*

q) *general: terms used to refer to client, occupation, sex acts, other relevant vocabulary*



CODE NO: ☐☐☐☐☐☐

Data recording form for C5(i): Interviews with female sex workers

DATE: INTERVIEWEE:

LOCATION: INTERVIEWER:

Address (general area, e.g. neighbourhood):

Age: *Marital Status:* *Children, if any:*

Any other occupation:

Educational level: *Estimated socio-economic status:*

Data Collection Guide for C5(ii): Men who have sex with men

Record background information on:

- *Location (general area, not address) of residence and of sexual encounters*
- *Age*
- *Marital Status*
- *Occupation*
- *Educational level*
- *Estimated socio-economic status*

Record information on:

a) *how long interviewee has been living in present place and where from, if not native of place*
b) *details of occupational and leisure activities*
c) *sexual history and details of where interviewee meets sex partners, how often*
d) *details of places locally where men can meet other men for sexual relations, how encounters are arranged and where any sexual acts take place*
e) *if interviewee gets paid for sex with men:*

- *what kinds of clients are seen - ages, occupations, places of residence, marital status*
- *how many clients were seen yesterday; how many are seen on average daily or weekly*
- *proportions of regular and new clientele - how often do regulars come*
- *what kinds of requirements do clients have (types of sex demanded and given, whether they eat/drink alcohol when meeting, where they meet, where they have sex)*
- *details of payment (how much is charged for each type of service, how much of the payment is then given to others and to whom)*
- *details of condom use (what proportion of clients use condoms; whether interviewee or client asks for their use and if supplied by interviewee, where are condoms obtained)*

f) *do any health problems arise from sex with men (symptoms and names of diseases)*
g) *details of any such health problem that interviewee has had, including*

- *nature of problem and details of symptoms*
- *what was done including treatment-seeking*
- *from where advice and treatment were obtained*
- *costs incurred and results*

h) *perceptions of cause, risk and prevention, including*

- *which diseases are sexually transmitted*
- *which are not sexually transmitted*
- *any other health problems associated with sex*
- *who is likely to get them*
- *how can they be avoided*

i) *any other problems, such as violence, related to having sex with men, problems with police, with family/household members, social stigma experienced*
j) *general: collect words used to refer to sex partners, sex acts and other relevant vocabulary*

CODE NO: ☐☐☐☐☐☐

Data recording form for C5(ii): Men who have sex with men

DATE: INTERVIEWEE:

LOCATION: INTERVIEWER:

Address (if appropriate; or general area of residence):

Age: *Marital Status:*

Occupation:

Educational level: *Estimated socio-economic status:*

Data Collection Guide for C5(iii): Interviews with others at high risk

Record background information on

- *Location (general area) of residence and of HRB*
- *Age*
- *Sex*
- *Marital status*
- *Occupation*
- *Educational level*
- *Estimated socio-economic status*

Record information on:

a) *how long interviewee has been living/working in present place (as appropriate) and where from, if not native of place*
b) *details of occupational and leisure activities, mobility patterns*
c) *sexual and marital history and details of non-marital sexual relationships (both pre and extra marital)*
d) *who works/are the sex partners (whether related or from neighbourhood, friends circle)*
e) *frequency and location of sexual interaction, type of sex engaged in, use of condoms*
f) *if interviewee pays or is paid indirectly or is coerced for sex:*

- *where is/are commercial sex partner(s) found, how often are they seen and any regular relationships*
- *details of transaction - where they meet, for how long, types of sex engaged in, details of others present, whether they eat/drink alcohol when meeting, where they have sex*
- *details of payment (how much is paid/received, whether directly to/from sexual partner or not, other non-cash gifts or services)*
- *details of condom use (whether used and with whom; whether sexual partner(s) of interviewee ever suggests use; if supplied by interviewee, where are condoms obtained)*

g) *do any health problems arise from sex (details of symptoms and names of diseases)*
h) *if so, what are causes, do they arise from sex generally or only with particular contacts, how can they be prevented, any obstacles to prevention*
i) *details of any such health problem that interviewee has had, including*

- *nature of problem and details of symptoms*
- *what was done including treatment-seeking*
- *from where advice and treatment were obtained*
- *costs incurred and results*

j) *perceptions of cause, risk and prevention, including*

- *which diseases are sexually transmitted*
- *which are not sexually transmitted*
- *any other health problems associated with sex*
- *who is likely to get them*
- *how can they be avoided*

k) *any other problems, such as violence, social disapproval, family problems related to having sex outside marital relationship*
l) *general: collect words used to refer to sex partners, sex acts and other relevant vocabulary*

CODE NO: ☐☐☐☐☐☐

Data recording form for C5 (iii): Interviews with others at high risk

DATE: INTERVIEWEE:

LOCATION: INTERVIEWER:

Address (general area):

Age: *Sex:* *Marital Status:*

Occupation:

Educational level: *Estimated socio-economic status:*

Data Collection Guide for D1: Surrogate client visits

Use this surrogate client history (the 'client' will narrate the following details to the practitioners) and add socio-demographic details appropriate to the 'client':

Complain of burning pain while urinating.

If asked: give actual age.
If asked about discharge, say there is a little clear discharge on waking in the mornings, but not at other times.
If asked about how long this has been going on, say for about 5 days.
If asked about recent sexual contacts, say with sex worker 10 days ago; before that was 6 months ago. Cost of sex: Rs. 100/-.
If asked where contact took place, say name of a known location for prostitution in the area (in the site itself if a large city, or else in a town of the same geographical region).
If asked further details, say visited area with some friends from elsewhere or for some work.
If asked place of residence, say name of a known town or suburb not in immediate vicinity.
If asked occupation: lower middle-class occupation appropriate to setting (e.g. small businessman; travelling salesman); if younger surrogate client, say student.
If asked whether the same symptoms had been experienced before, say same thing 2 years ago, you don't know what it was but took tablets given to you by a friend and it got better.
If asked about condom use: say condom not used. If asked further: say have never used a condom.
If asked: For older actor say married and if asked say 2 children (1 boy; 1 girl - determine ages appropriate to surrogate client's age); for younger actor say unmarried.
If asked if you have heard about AIDS - say yes but you know little about it.
If asked about other medical problems: no.
Extemporise answers to any additional questions but do not volunteer any information.

****

Data recording

Try and remember the questions the doctor asks as much in his/her own exact words as you can. In particular, record whether the doctor asks about (1) the nature of your symptoms (2) how long you have had these symptoms (3) your recent sexual encounters. Also try and remember your exact replies to these and anything else you said. Record or describe during debriefing afterwards. Also record the name of the doctor, the address of location of the clinic and the doctor's qualifications and area of specialisation as given on the sign board (if any).

CODE NO: ☐☐☐☐☐☐

Data recording form for D1: Surrogate client visits (page 1 of 2)

DATE:
NAME OF PRACTITIONER:
INTERVIEWER INITIALS:

Name, address and location of Clinic:

Medical speciality and qualifications of treatment provider actually seen:

Write a description of the consultation in the order in which it happens, recording the actual words of the practitioner as far as possible and including details on the following points.

Record the examination the doctor performs. To what extent are clothes removed and genitals fully exposed? Does the doctor perform careful inspection, with foreskin retraction? Does (s)he attempt to express discharge? Does (s)he ask you to do these things? Does (s)he want to perform any tests (take blood or urine samples) or send you elsewhere to have tests performed (if so, retain referral slips)?

What does (s)he tell you about the condition he thinks you have?

Did you have to ask for the condition or did the doctor himself/herself tell you about it?

What treatment does (s)he prescribe? (keep prescription).

What advice does (s)he give regarding
(1) how / when /for how long you should take medication;
(2) whether you should use condoms;
(3) whether you should refer your sexual partner(s) for treatment;
(4) other advice.
Is AIDS / HIV mentioned during the consultation?

What does (s)he suggest regarding return visits to see him?

What does (s)he charge? Does (s)he suggest a particular place for purchasing the medicines?

CODE NO: ☐☐☐☐☐☐

Data recording form for D1: Surrogate client visits (page 2 of 2)

Data Collection Guide for D2(i): Interviews at pharmacies/medicine shops

Record background information on

- *Name and Address of Establishment*
- *Contact telephone numbers*

Record information on:

a) *Who generally uses the pharmacy/medicine shop (population served, any particular communities)*
b) *What are the most common complaints which people buy medicines for (if not mentioned, ask about skin problems and 'hidden' diseases, sexual diseases)*
c) *Do people ask for advice about how to treat particular health problems or symptoms and if so, who provides this (pharmacy assistant or pharmacist)*
d) *Do many people buy drugs for treating 'hidden diseases'/'VD'? (use appropriate local terms if different)*
e) *What types of person buy them?*
f) *Do people ever ask for medicines by describing symptoms which suggest such conditions? If so, what advice are they given?*
g) *Do people ever ask for antibiotics by name? Which ones?*
h) *Do you sell condoms? Roughly how many do you sell per week? What kinds of customers buy condoms?*
i) *How many people work in the pharmacy/medicine shop and staffing patterns (including times when pharmacist attends if not full time)*

Data Collection Guide for D2(ii): Observations at pharmacies/medicine shops

Record background information on

- *name and address of shop*
- *contact telephone numbers*

Record information on:

a) *numbers and types of transactions seen (actual buying and selling of medicines)*
b) *numbers and types of transactions in which customer asks only for a type of medicine (which medicines are these)*
c) *numbers and types of transactions in which customer describes symptoms and requests appropriate treatment (note particularly any symptoms likely to be related to infections of interest to SASHI like those related to skin/genitals)*
d) *numbers of transactions in which customer requests condoms*
e) *whether condoms openly displayed and types available*
f) *characteristics and nature of clientele*
g) *any other relevant observations*

CODE NO: ☐☐☐☐☐☐

Data recording form for D2: Interviews and observations at pharmacies/medicine shops

DATE:

INTERVIEWEE:

LOCATION:

INTERVIEWER:

Name and Address of Pharmacy:

Contact telephone numbers if available:

Record background information on

- *Name and Address of Establishment*
- *Contact telephone numbers*
- *Allopathy/homeopathy/ayurveda/non-qualified*
- *Public/Private Clinic*
- *Medical Speciality (e.g. dermato-venereology,gynaecology, general)*

Record information on:

a) *Number of other practitioners working in same establishment, if any*

b) *How many years has interviewee been qualified/working in this speciality*

c) *How many years has the interviewee been working in this location*

d) *Number of STD patients seen in the last week in facility*

e) *Number of STD patients seen in an average week in facility*

f) *Who uses the facility generally (population served and their characteristics)*

g) *Are patients seen on any particular days? At any particular times of day?*

h) *Which STDs are seen and how common is each (in order of frequency)*

i) *What are the characteristics of the patients who come with these problems (ages, occupations, from where they come, male/female)*

j) *How long have they usually had the STD before coming for treatment?*

k) *How do the patients understand these conditions (patients' perceptions)*

l) *What kind of treatment does the health provider give?*

m) *Does he/she offer treatment to the partner of the patient - if so, how (referral or provision of medicines to patient)?*

n) *Is any other advice given to patient? If not mentioned spontaneously, then ask if advice is given on condom use. Also if not mentioned spontaneously, then ask if any information is given about HIV/AIDS infection to patient.*

o) *Where else do people with STDs go for treatment (including self-medication)?*

p) *Why do they think STDs occur in this site (assess attitude of provider to patients and to sexual health and disease prevention - this can also be assessed indirectly from other responses)?*

q) *Are there any particular difficulties and concerns associated with their work?*

CODE NO: ☐☐☐☐☐☐

Data recording form for D3: Interviews with practitioners

DATE: INTERVIEWEE:

LOCATION: INTERVIEWER:

Name and Address of Clinic:

Contact telephone numbers:

Public/Private (delete as necessary)

Medical speciality:

Number of other practitioners working in same establishment, if any: [ ]

How many years has interviewee been working in speciality/and in present location? [ ] [ ]

Number of STD patients seen in the last week in clinic. . . . . [ ] [ ]

Number of STD patients seen in an average week in clinic. . [ ] [ ]

Code No: ☐☐☐☐☐☐

Data recording form for D4: Practitioners providing STD treatment

Record of STD patients seen at health facilities

Facility name..... Practitioner completing form .....

Period of data collection: from ...../...../..... to ...../...../..... Sheet number .....

Date	Sex M/F	Age	Complaint (according to patient)	Tests (if any)	Diagnosis	Treatment

Data Collection Guide for D5(i): Exit interviews with STD patients

Record background information on

- *Age*
- *Marital status*
- *Education*
- *Occupation*
- *Place (general area) of residence*

a) *Can you tell me about the problem for which you came here today and how you described it to the practitioner?* [Ask interviewee to describe symptoms if necessary and record their own words exactly, especially terms used for symptoms, body parts and sexual contacts]
b) *What did he/she do after you explained your problem* [management practices]*?*
c) *What treatment have you been given* [prescribing practices]*?*[Record details on prescription if offered]. *Will you take it* [the treatment]*?*
d) *Did the practitioner ask you any questions?* (record the questions)
e) *Were you given any other advice at all? (if not mentioned probe about whether any advice was given on condoms, HIV/AIDS, partner referral)*
f) *Have you been told by the practitioner what your problem is?*
g) *Do you think that is correct?* [find out patient's perception of problem]
h) *When were you first aware that there was a problem?*
i) *And then what did you do?* [Seek details of behaviour and treatment history].
j) [If not mentioned -] *Have you tried any other source of treatment before coming here?* [probe on self-medication and other non-professional treatment forms if necessary, also on sources of informal advice: did they talk to a friend, had they had such a symptom before, etc. If self-medication mentioned, record details of how the medicine was obtained (e.g. whether by getting the name of a medicine (who from?) and asking for it at a pharmacy; using an old prescription from a previous consultation; being given some medicine by a friend; describing the symptoms at a medicine shop and asking for medicine, etc.)
k) [If not mentioned -] *How in your opinion did you get this?* [obtain details & history of sexual behaviour if not already given - pre-/extra-marital sexual contacts, where & when]
l) *Is there anything you feel you can do to avoid such a problem in future?*
m) *Are there any obstacles to avoiding such a problem/reasons why this may be difficult?*
n) *Why did you come to this particular practitioner?* [how did they know where to find treatment, had they heard the name before & who from, had they been here before etc.]
o) *How do you feel about the treatment you have received? If you had a similar problem again, would you consider coming back here?*

Data Collection Guide for D5(ii): Exit interviews with STD patients in participating clinics

Record background information on

- *Age*
- *Marital status*
- *Education*
- *Occupation*
- *Place (general area) of residence*

a) [If not known] *Can you tell me about the problem for which you came here today?* [Ask interviewee to describe symptoms if necessary and record details]

b) *How did you describe it to the doctor?*[record patient's own words used for symptoms, body parts and sexual contacts]

c) *When were you first aware that there was a problem?*

d) *And then what did you do?* [Seek details of behaviour and treatment history]

e) *What do you think is wrong with you?* [patient's perceptions of problem & cause]

f) If not mentioned, ask] *Have you tried any other source of treatment before coming here?* [ask about self-medication and other non-professional treatment forms, also on sources of informal advice: where did they get the name of the medicine they used, did they talk to a friend, had they had this symptom before]

g) If previous treatment is described, enquire about the following issues:

- *What did the practitioner do?* [management practices - was an examination performed? Were any tests ordered?]
- *What treatment was given* [prescribing practices]*?*[Record details on prescription if available or patient's own account]. *Did you take it* [the treatment]*?*
- *Did the practitioner ask any questions?* [find out if sexual contacts was asked about]
- *Was any other advice given?* [e.g. condom promotion, advice on sexual contacts, partner referral, information on HIV/AIDS]
- *How does the patient feel about the treatment received then?* [satisfaction level]

h) If self-medication is mentioned, enquire in detail how the medication was obtained (e.g., whether by getting the name of a medicine (who from?) and asking for it at a pharmacy; using an old prescription from a previous consultation; being given some medicine by a friend; describing the symptoms at a medicine shop and asking for medicine, etc.)

i) [If not already mentioned -] *How in your opinion did you get this?* [ask details & history of sexual behaviour, including previous extra-marital sexual contacts, where and when]

j) *Is there anything you feel you can do to avoid such a problem in future?*

k) *Are there any difficulties in doing this/What are the obstacles to avoiding or preventing such problems?*

l) [If not already mentioned] *Why did you come to this particular clinic today?* [how did they know where to find treatment, had they been told about the Department & who from, had they been here before etc.]

Data Collection Guide for D5(iii): Exit interviews with STD patients by consulted practitioner

Record background information on

- *Age*
- *Marital status*
- *Education*
- *Occupation*
- *Place of residence*

a) [If not known] *Can you tell me how you would normally describe the problem for which you came here today, for instance to a friend?* [record patient's own words especially terms used for symptoms, body parts and sexual contacts]

b) When were you first aware that there was a problem?

c) And then what did you do? [Seek details of behaviour and treatment history].

d) [If not mentioned already] *Have you tried any other source of treatment before coming here?* [probe on self-medication and/or other non-professional treatment forms if necessary, also on sources of informal advice: where did they get the name of the medicine they used, did they talk to a friend, had they had this symptom before, etc. If self-medication is mentioned, enquire in detail how the medication was obtained, e.g. whether by getting the name of a medicine (who from?) and asking for it at a pharmacy; using an old prescription from a previous consultation; being given some medicine by a friend; describing the symptoms at a medicine shop and asking for medicine, etc.]

e) [if first visit] *Why did you come to my particular clinic?* [probe on how did they know where to come for treatment, had they heard of the name before and from whom, etc.]

f) [If not mentioned -] *How in your opinion did you get this problem?* [probe on details and history of sexual behaviour if not previously covered, including any previous extra-marital sexual contacts, where and when]

g) [If preventive action not already discussed or only partly discussed] *Is there anything [else apart from what I have mentioned] that you feel you can do to avoid such a problem in future? Are there any difficulties or obstacles in trying to avoid such problems?*

CODE NO: ☐☐☐☐☐☐

Data recording form for D5: Exit interviews with STD patients

DATE:

INTERVIEWEE:

LOCATION:

INTERVIEWER:

Age:

Marital Status:

Educational level:

Place (area) of residence:

Occupation:

Data Collection Guide for D6 (additional step): Surrogate client visits to pharmacies

Surrogate client history (the 'client' will narrate the following details to the pharmacist or shop assistant)

[To be completed by medical supervisor in consultation with social science supervisor. The guidelines on the consultation should include how the surrogate client is to approach the pharmacist/shop assistant - using an old prescription? asking for a particular drug? offering a self-diagnosis? describing symptoms and asking for help? - and specify whether the client should consult the first person in the shop who is available or ask for the pharmacist in person.]

CODE NO: ☐☐☐☐☐☐

Data recording form for D6: Surrogate client visits to pharmacies (page 1 of 2)

DATE:
NAME OF PHARMACY:
INTERVIEWER INITIALS:

Address and location of Clinic:

Tick which one(s) of the following consultation approaches was used:
Using an old prescription? [ ]
Asking for a particular (named) drug? [ ]
Offering a self-diagnosis and asking for medicine? [ ]
Describing symptoms and asking for help? [ ]

Write on additional sheets a description of the visit in the order in which it happens, recording the actual words of the pharmacy or pharmacy assistant as far as possible. Specify whether a pharmacist or a shop assistant, or both, were consulted. Also answer for each approach used:
Did the approach work?
If yes, did it require persuasion (describe)?
If no, what was the interaction (describe)?

What did the pharmacist/assistant tell you about the condition s/he thinks you have?

Were symptoms recognised as STD related? [Yes/No]
What treatment did (s)he suggest?

If medication was offered, which drugs were provided? (keep packet if purchased or record details of name, amount and cost suggested for purchase)

Was referral to a physician suggested? [Yes/No]
If Yes, was a named physician recommended? [Yes/No]
Was partner treatment suggested? [Yes/No]
Were condoms recommended? [Yes/No] offered? [Yes/No] provided? [Yes/No]
Was AIDS / HIV mentioned during the consultation? [Yes/No]

Record verbatim (the exact words used) on attached sheets what other advice, if any, was given regarding:

CODE NO: ☐☐☐☐☐☐

Data recording form for D6: Surrogate client visits to pharmacies (page 2 of 2)

(1) how / when /for how long you should take medication;
(2) the importance of adhering to any prescribed treatment;
(3) whether you should avoid risky sexual practice;
(4) whether you should refer your sexual partner(s) for treatment;
(5) whether you should abstain from sexual relations with partner until they are treated;
(6) other advice.

For completion by medical supervisor:
Did the suggested medication include
- drugs recommended in National/WHO guidelines for the symptoms presented? [Yes/No]
- the recommended dosage? [Yes/No]

Data collection guide for E1: Male STD study / E2: Additional urethritis study / E3: Female RTI study

CODE NO: ☐☐☐☐☐☐

Name

Please read the following out to the potential participant in local language

"Hello! I am.....

I am a physician. Presently I am working with the Government of ..... and other physicians of this locality on a project (SASHI) through which we are trying to understand the diseases of the skin and genitourinary system better.

If you agree to participate in this project, I will ask you a few questions and will also take samples from you (swabs, blood etc.) for laboratory investigations. We will tell you your test results free of cost. Of course the information you will be providing for the study as well as the test results, will remain strictly confidential.

Straight and honest responses from you will help me in conducting this interview. It would also help us in reaching a diagnosis for your present symptoms for which you have come to this clinic".

(If the clinic attender agrees to participate, go ahead with the data collection, otherwise thank him/her and terminate the interview).

I hereby voluntarily agree to participate in the study that has been explained to me in detail by the above mentioned doctor and who has also read out the above writing to me.

Signature or Left thumb Impression (LTI)
of the participant

cut here.....

Code number

Name

CODE NO: ☐☐☐☐☐☐

Data recording form for E1: Male STD study/ E2: Additional urethritis study / E3: Female RTI study

Date: (dd/mm/yy) ..... Clinic: .....

1. Demographic data: (circle as appropriate)

A. Sex: M / F

B. Age: (Include only persons of 15 years and above) ..... years

C. Marital status: 1) Married / 2) Separated / 3) Divorced / 4) Widowed / 5) Never married

D. Occupation of the participant: .....

E. Educational status: graduate / non graduate

2. History. *For what reasons or illnesses have you come to this clinic?* (ask about the presenting symptoms; do not read out or prompt any of the following; just ask "anything else" after each symptom mentioned). Circle Y or N as appropriate. Make sure you circle either Y or N for each presenting complaint.

A.	Burning sensation during urination	Y / N
B.	Discharge from urethra	Y / N
C.	Discharge from vagina	Y / N
D.	Pain on intercourse	Y / N
E.	Itching over the vagina	Y / N
F.	Ulcer on or around the genitalia	Y / N
G.	Swelling of the groin	Y / N
H.	Swelling of the sex organ	Y / N
I.	Growth (small / big) on or around the genitalia	Y / N
J.	Any symptoms in the anal region or rectum	Y / N
K.	Other	Y / N

(in participant's own words)

CODE NO: ☐☐☐☐☐☐

3. ***What did you do for the present illness before coming to this clinic?*** **(read out all of the following options one by one and circle accordingly for each one)**

A. Asked for advice from friends or family and bought medicines Y / N

B. Asked for advice from pharmacy and bought medicines Y / N

C. Bought medicines on own initiative Y / N

D. Visited non-RMP traditional healers Y / N

E. Visited registered medical practitioners (RMP) Y / N

if YES to E: which kind of RMP? .....

F. Visited specialist (M.D.) Y / N

(please specify which discipline/medical tradition).....

G. Others (please specify)..... Y / N

Time sequence of the above actions taken by the participant (**fill in boxes with the letter of each action taken in the order that the participant has taken it, after asking for extra details if necessary, e.g. C E D F**)

4.1 Please ask: ***Did you use any of the following for the present illness before coming to this clinic***

A. Tablets Y / N

B. Capsules Y / N

C. Injection Y / N

D. Local applications / ointments / vaginal pessaries Y / N

E. Others (please specify) ..... Y / N

4.2 Please ask about the details of the previous treatment, as far as the patient can remember. In your opinion, do you (the doctor) think that the treatment has been appropriate? Y / N

5. History of recent sexual behaviour (please mention that ***"I am going to ask you questions on your sexual behaviour. Don't feel embarrassed. All your responses will remain completely confidential. A truthful response will help me in arriving at a proper diagnosis"*****)**

A i) *During the last 3 months did you have sex with your husband / wife?* Y / N / X (X = not applicable)

A ii) *The last time you had sex with your husband / wife, did you use a condom ?* Y / N / X

B i) *During the last 3 months did you have sex with a regular partner to whom you are not married ?* Y / N

B ii) *The last time you had sex with this regular partner, did you use a condom ?* Y / N / X

Ci) *During the last 3 months did you have sex with a casual partner (*for men only*: unpaid)?* Y / N

Cii) *The last time you had sex with this casual partner, did you use a condom ?* Y / N / X

Di) ask men only: *During the last 3 months did you have sex with a casual partner and pay for it ?* Y / N / X

Dii) The last time you had sex with this casual partner, did you use a condom ? Y / N / X

6. (ask men only) *Have you ever had sex (to ejaculation) with a man?* Y / N / X

7. Signs: (please wear a pair of gloves to milk the male urethra if necessary and to palpate any ulcers to check for induration and tenderness, and also to carry out a bimanual palpation in case of a female patient)

A. In men: Urethral discharge: Present / Absent / X

B. In women: Vaginal discharge: Present / Absent / X

C. Ulcer on or around the genitalia: Present / Absent

D. Swelling of the inguinal lymph nodes: Present / Absent

E. Infection and inflammation of the glans penis (balanitis) Present / Absent / X

F. Warts Present / Absent

G. Growth around anus — Present / Absent

H. Fissure or ulcer around anus — Present / Absent

I. Anal discharge — Present / Absent

J. In women on bimanual palpation:

i) Is the fornix tender? — Y / N / X

ii) Is the fornix clear? — Y / N / X

iii) Is there an abdominal mass? — Y / N / X

iv) Cervical tenderness on movement? — Y / N / X

K. Alterations of the cervix uteri on speculum exam.? — Present / Absent / X

If present:

i Cervical ectopy — Y / N / X
ii Cervical inflammation — Y / N / X
iii Cervical mucopus — Y / N / X
iv Cervical ulcer — Y / N / X
v Cervical growth / warts — Y / N / X

L. P_H of the vaginal fluid — / X

CODE NO: ☐☐☐☐☐☐

8. Incomplete examination :

A Was a full genital examination possible (as designed for this study)? Y / N

B If "N" to question 8A please state why (e.g. patient is virgin)

.....

9. What is your presumptive diagnosis? .....

.....

10. What is the basis for this diagnosis? (in brief) .....

.....

.....

CODE NO: ☐☐☐☐☐☐

Data collection guide for E4: ANC study

Name

Please read the following out to the potential participant in local language

"Hello!

I am .....

I am a physician. Presently I am working with the Government of [give name of State eg. Kerala] and other physicians of this hospital on a project (SASHI) through which we are trying to understand the health and well-being of pregnant women better.

If you agree to participate in this project, I will ask you a few questions and will also take samples from you (swabs, urine and a little blood) for laboratory investigations. We will inform you about your test results free of cost. Of course the information you will be providing for the study as well as the test results, will remain strictly confidential.

If the clinic attender agrees to participate, go ahead with the data collection, otherwise thank her and terminate the interview.

Consent:

"I hereby voluntarily agree to participate in the study that has been explained to me in detail by the above mentioned doctor and who has also read out the above writing to me".

Signature or Left thumb Impression (LTI)
of the participant
cut here.....

Code number

Name

CODE NO: ☐☐☐☐☐☐

Data recording form for E4: ANC study

Date: (dd/mm/yy) ..... Clinic: .....

1. Demographic data: (circle as appropriate)

A. Age: ..... years

B. Marital Status: 1) Married / 2) Separated / 3) Divorced / 4) Widowed / 5) Never married

C. Education: 1) Graduate / 2) Non-graduate

D. Occupation of the participant: .....

E. Occupation of the spouse: .....

2. Reported symptoms: *"I am going to ask you a few questions which relate to infections which may influence the health of your baby which is going to be born. - Do you have any problems with your pregnancy or any problems with your genital or urinary region ?"*

Do not prompt! Just ask 'anything else? after the pregnant woman has finished. Circle Y for any information given spontaneously by the woman. If symptoms are not spontaneously mentioned, circle N. Ensure you circle either Y or N on each line.

A. Burning sensation during urination	Y / N
B. Discharge from vagina	Y / N
C. Itching over the vagina	Y / N
D. Ulcer on or around the genitals	Y / N
E. Swelling of the groin	Y / N
F. Growth / warts on or around the genitalia	Y / N
G. Pain of lower abdomen	Y / N
H. Others	Y / N

(please describe in participants own words) .....

CODE NO: ☐☐☐☐☐☐

3. Obstetric history (ask all of the following) :

A How many previous pregnancies have you had? .....

B How many previous live births have you had? .....

C How many stillbirths or intrauterine deaths have you had? .....

D How many spontaneous miscarriages have you had? .....

E How many therapeutic abortions (MTPs) have you had? .....

F Did you have any pre-term delivery during previous pregnancies? Y / N / X

(circle 'X' for 'not applicable' in case of a primigravida)

4. *Have you had a dilatation and curretage (D & C)* Y / N

5. *Have you ever used an IUCD?* Y / N

6. Signs on examination:

A Excessive vaginal discharge: Present/ Absent

B Ulcer on or around the genitals: Present / Absent

C Swelling of the inguinal lymph nodes: Present/ Absent

D Alterations of the cervix uteri on speculum exam.? Present/ Absent

If present:

D.i Cervical ectopy Y / N / X
D.ii Cervical inflammation Y / N / X
D.iii Cervical mucopus Y / N / X
D.iv Cervical ulcer Y / N / X
D.v Cervical growth / warts Y / N / X

E Alterations of the anal region ? Y / N

E.i If yes, which ones? .....

7. Do you have any presumptive diagnosis of a genito-urinary disease ? Y / N

7 a. If yes, what is it and what is the basis of your diagnosis ? .....

.....

CODE NO: ☐☐☐☐☐☐

Data collection guide for E5: Additional ANC study

Name

Please read the following out to the potential participant in local language

"Hello!

I am .....

I am a physician. Presently I am working with the Government of ..... and other physicians of this hospital on a project (SASHI) through which we are trying to understand the health and well-being of pregnant women better.

If you agree to participate in this project, I will ask you a few questions and will take a urine sample from you. Of course the information you will be providing for the study will remain strictly confidential.

If the clinic attender agrees to participate, go ahead with the data collection, otherwise thank her and terminate the interview.

Consent:

"I hereby voluntarily agree to participate in the study that has been explained to me in detail by the above mentioned doctor and who has also read out the above writing to me".

Signature or Left Thumb Impression (LTI)
of the participant

CODE NO: ☐☐☐☐☐☐

Data recording form for E5: Additional ANC study

Date: (dd/mm/yy) ..... Clinic: .....

1. Demographic data: (circle as appropriate)

A. Age: ..... years

B. Marital Status: 1) Married / 2) Separated / 3) Divorced / 4) Widowed / 5) Never married

C. Education: 1) Graduate / 2) Non-graduate

D. Occupation of the participant: .....

E. Occupation of the spouse: .....

2. Reported symptoms: *"I am going to ask you a few questions which relate to infections which may influence the health of your baby which is going to be born. - Do you have any problems with your pregnancy or any problems with your genital or urinary region ?"*

Do not prompt! Just ask 'anything else? after they have finished. Circle Y for any information given spontaneously by the pregnant woman. If symptoms are not spontaneously mentioned, circle N. Ensure you circle either Y or N on each line.

A.	Burning sensation during urination	Y / N
B.	Discharge from vagina	Y / N
C.	Itching over the vagina	Y / N
D.	Ulcer on or around the genitals	Y / N
E.	Swelling of the groin	Y / N
F.	Growth / warts on or around the genitalia	Y / N
G.	Pain of the lower abdomen	Y / N
H.	Others	Y / N

(please describe in participants own words) .....

CODE NO: ☐☐☐☐☐☐

3. Obstetric history: (ask all of the following)

A *How many previous pregnancies have you had?* .....

B *How many previous live births have you had?* .....

C *How many stillbirths or intrauterine deaths have you had?* .....

D *How many spontaneous miscarriages have you had?* .....

E *How many therapeutic abortions (MTPs) have you had?* .....

F *Did you have any pre-term delivery during previous pregnancies?* Y / N / X:

(mark 'X', which means 'not applicable', in case of a primigravida)

4. *Have you had a dilatation and curretage (D & C)* Y /N

5. *Have you ever used an IUCD?* Y / N

6. Do you have any presumptive diagnosis of a genito-urinary disease ? Y / N

6 a. If yes, what is it and what is the basis of your diagnosis ? .....

.....

CODE NO: ☐☐☐☐☐☐

Data collection guide for E6: Male General Population Study

Please read the following out to the potential participant in local language

"Hello!

I am .....

I am a physician. Presently I am working with the Government of ..... and other physicians of this locality on a project through which we are trying to understand better the health and well-being of people in _____. [name of research site]

If you agree to participate in this project, I will ask you a few questions and will collect a urine sample from you. This set will be tested (including an instant dipstick test) which will allow us to detect if you have early stages of diabetes and also signs of other disease of the kidneys and urinary system. We will provide instant feedback on the results of the dipstick test to you if you would like. Of course the information you will be providing for the study as well as the test results, will remain strictly confidential.

(If the man agrees to participate, go ahead with the data collection, otherwise thank him and terminate the interview)

Consent:

I hereby voluntarily agree to participate in the study that has been explained to me in detail by the above mentioned doctor and who has also read out the above writing to me.

Signature or Left Thumb Impression (LTI)
of the participant

Name .....

(please check that each person participates only once):

CODE NO: ☐☐☐☐☐☐

Data recording form for E6: General Population Study Form

(circle answers as appropriate) Date: (dd/mm/yy) .....

1. Age: ..... years
2. Marital status: Married / Separated / Divorced / Widowed / Not married
3. Education: graduate / non-graduate
4. Occupational level .....
5. *Have you ever been told you have high blood pressure?* Y / N
6. *Does any immediate (blood) relative have high blood pressure?* Y / N
7. *Have you ever been told you have diabetes?* Y / N
8. *Does any immediate (blood) relative have diabetes?* Y / N
9. *Have you noticed any change in your thirst over the last year?* Y / N
10. *Have you noticed any change in the frequency with which you pass urine in the last year?* Y / N
11. *Do you have pain (or burning sensation) on passing urine?* Y / N

    IF YES : *How long have you had this for?* ..... years/or ..... weeks/or ..... days
12. *Have you ever had pain (or burning sensation) on passing urine?* Y / N

    IF YES : *When was the last occasion?* ..... years/or .....weeks/or ..... days ago
13. *Did you obtain treatment for this?* Y / N / X

    IF YES : Record details of treatment .....

    .....
14. *When did you last pass urine?* ..... hours ..... minutes ago

If more than 1 hour collect urine sample: otherwise ask to wait or come back after there has been a 1 hour gap.

Only the very first portion of the urine should be collected, NOT the total void !

Urine sample successfully collected Y / N

Mark urine collection container with name of patient, so that dipstick result can be provided to the respective individual.

Transfer about 1 ml of urine from each sample into two 1.5 ml vials. Do not mark vials.

APPENDIX 5.2

LABORATORY GUIDELINES

5.21: PROCEDURES FOR CONDUCT OF TESTS

5.22: LABORATORY QUALITY CONTROL PROCEDURES

Appendix 5.21: Laboratory guidelines

Table 1: LABORATORY TESTS FOR MEDICAL STUDIES (STAGE E)

DISEASE (STD/RTI)	LABORATORY TEST/S
1. Syphilis	a. VDRL b. TPHA
2. HIV infection	a. ELISA - twice b. For confirmation samples may be sent to NICD, AIIMS, HIV, Vellore Medical College, other official centre
3. Chlamydia infection	a. Chlamydia antigen ELISA b. Chlamydia PCR
4. Herpes simplex infection	a. Herpes simplex antigen ELISA
5. Trichomonal vaginosis	a. Wet smear
6. Candidial vaginosis	a. Gram stain
7. Gonorrhoea	a. Smear-gram stain b. Culture on theyer martin medium c. E test for drug resistance d. PCR
8. Bacterial vaginosis	a. Smear-gram stain (grading the smear to decide about bacterial vaginosis)
9. General check-up	a. Urine-albumin and sugar dipstick method

The above table summarises various laboratory tests that need to be undertaken within SASHI for different conditions that are studied. Careful handling of the clinical samples and monitoring of laboratory procedures is critical for obtaining valid results from laboratory tests. An outline of laboratory sample handling and processing is provided here.

For *VDRL, TPHA and HIV tests,* blood should be collected aseptically using the vacutainer system. After allowing 2 hours for clotting of blood, serum should be separated by centrifuging. Separate Pasteur pipette/micropipette tips should be used for each sample and stored in cryovials. The samples should then be stored in a refrigerator until the test is performed.

VDRL and RPR Test

VDRL is a non specific test for syphilis which detects "Reagin" type antibodies. Reagin antibodies appear within 10 - 15 days of infection and disappear if the patient is treated adequately. The instructions provided with the VDRL kit should be followed. If VDRL liquid antigen is used, then VDRL well slides are required and each slide should be inspected under low power microscopy for the presence of flocculation. If the test is positive, then serum should be diluted 1:2; 1:4; 1:8; 1:16; 1:32 and 1:64 to establish the titre. Titres of 1:8 and higher levels of dilution are considered diagnostic of syphilis. RPR card tests also detect reagin antibodies and they are recommended for use instead of the VDRL test where possible. As with VDRL, the highest titre should be established for positive tests. RPR should be done in conjunction with the TPHA test described below:

Treponenra pallidium haemagglutination (TPHA) test

This indirect haemagglutination test is a specific test for syphilis. Guidelines provided with the kit should be followed. Formation of a "button" appearance indicates a negative test, while the formation of a "carpet" appearance indicates a positive test. Specific antibodies appear 2 to 3 weeks after infection and generally persist throughout life, even following successful treatment.

Where possible, both RPR and TPHA tests should be performed and their results interpreted in conjunction, as follows:

TPHA negative, RPR positive	-	false positive RPR reaction or very early phase of ulcerative syphilis
TPHA positive, RPR positive	-	primary, secondary or early latent phase (with high RPR titre)
TPHA positive, RPR positive	-	late latent phase, late syphilis, or past history of syphili (with low RPR titre) (after late treatment)
TPHA positive, RPR negative	-	past history of syphilis

If VDRL has to be used instead of RPR, the results should be interpreted in conjunction with TPHA as follows:

Only VDRL Positive	-	early stage syphilis
VDRL + TPHA Positive	-	later stage syphilis
Only TPHA Positive	-	past history of syphilis, without current active infection

N. Gonorrhea - Gram Stain

The smear should be prepared from the swab collected from urethral discharge by rubbing the swab in a circular fashion on the clean glass slide. The smear is fixed by passing the slide through a flame 2-3 times so that the slide becomes just warm to touch. The gram stain procedure is then followed. Decolourization should be performed until the purple colour fluid ceases to be observed. The slide is viewed under oil immersion microscopy and intracellular gram negative diplococci with a typical kidney shape and a profusion of pus cells are looked for. The absence of gram negative diplococci with the profusion of pus cells is suggestive of chlamydial infection and may be correlated with chlamydia antigen and PCR test results.

Trichomonas Vaginosis Wet Preparation

Vaginal discharge is collected on a wooden-shafted swab and applied to a glass slide. A drop of saline is added and a coverslip applied. The amount of saline should be adjusted to ensure that the material does not overflow the coverslip. The slide is inspected under the microscope for the highly motile trichomona with typical pear shape appearance and flagellae.

Candidial Vaginosis - Gram Stain

The gram stained vaginal discharge slide is inspected under microscopy for gram positive budding yeast cells.

Bacterial Vaginosis

The gram stain smear prepared for the detection of candida can be used for diagnosing bacterial vaginosis. The gram stained smear is graded for the presence of gram positive lactobacilli, small gram negative to gram stain variable curved rods, and gram negative curved rods. Details of the scoring system are described in **Nugent RP et al: Reliability of diagnosing bacterial vaginosis is improved by a standardised method of gram stain interpretation. J Clin Microbiol 1991; 29: 297-301.** Grade 7 and above is diagnostic of bacterial vaginosis. Two simplified tables for deciding morphotype score are also given below. Read the reference carefully, then score the smears with the help of Tables 2 and 3.

Table 2: Scoring for Vaginal Gram Stain

Score	Lacto Bacilli	Small G-negative to Gram variables rods (G.Vaginalis & Bacteroids)	Gram Negative Curved rods (Mobilincus species)
0	++++	0	0
1	++++	+	0
2	+++	+	0
3	+++	++	0
4	+++	+++	0
5	++	+++	0
6	++	++++	0
7	+	++++	0
8	0	++++	0
9	0	++++	++
10	0	++++	++++

Table 3: Morphotype Scoring

No. of Morphotypes	Score
0 Morphotype	0
<1 Morphotype	+
1-4 Morphotypes	++
5-30 Morphotypes	+++
30 or >30 Morphotypes	++++

Chlamydia Antigen ELISA

Chlamydia trachomatis is one of the important STD agents and produces urethritis, epididymitis and proctitis in males and cervicitis and pelvic inflammatory disease in females. Isolation of chlamydia on tissue culture is the ideal method of laboratory diagnosis. But this method is time consuming, costly and of low sensitivity. Direct antigen detection using ELISA is an alternative method to tissue culture. For chlamydia antigen detection, standardized kits are available commercially. Either Competitive Inhibition ELISA or Sandwich ELISA techniques are used in these kits.

The most important part of the procedure is extraction of antigen from the urethral swab using specimen treatment solution. This procedure should be done as early as possible after collection of a swab and as per guidelines given along with the kits. Follow the test procedure given in the kit leaflet meticulously to get accurate results.

Herpes type II Antigen ELISA

Genital Herpes is caused by Herpes type II virus and sometimes type I virus. It produces vesicular & ulcerative lesions on male genitals and chronic cervicitis in females. Prevalence of genital herpes is rapidly increasing in India. Laboratory diagnosis of genital herpes is usually done by isolation on tissue culture but the report is available in 48 hours and needs facilities for tissue culture.

Herpes Antigen ELISA is a simple and rapid alternative for virus culture. Competitive Inhibition ELISA or Sandwich ELISA technique is usually used in commercially available kits. Processsing of the genital ulcer swab or cervical swab with specimen treatment solution should be done as early as possible. Extracted antigen should be stored in a refrigerator after labelling it properly. The test should be carried out exactly as per the guidelines given in the test kit.

HIV 1 and 2 IgG ELISA

HIV 1 & 2 IgG ELISA is the most widely used test for the laboratory diagnosis of HIV infection. Commercially available kits are highly specific and sensitive as recombinant or synthetic envelope and gag antigens are used. Follow the protocol suggested by the National AIDS Control Organisation (NACO) for reporting HIV test results. As per NACO protocol, once found to be ELISA positive, a sample should be retested by ELISA or by using a rapid test kit from a different manufacturer. If the sample is positive by both the kits then only it should be reported as an HIV positive test. If one of the two tests is positive then the sample should be tested by western blot method for confirmation. If both the tests are negative then the sample is reported as negative. Follow the guidelines in the kit meticulously while doing the test. Pre-test and Post-test counselling should be given if the report is to be disclosed to the patient.

Polymerase Chain Reaction (PCR)

PCR is vitro DNA amplication technique. In this technique a highly specific portion of DNA to be amplified is used as a primer. These primers can be synthesized if the detailed aminoacid sequences of the DNA are known. Repeated cycles of denaturation, primer extension and annealing is carried out with heat stable enzyme taq polymerase. The end result is an exponential increase in the target DNA. PCR amplification can produce a large number (millions) of copies if even one molecule of DNA is present in the sample. For example even a single organism of N gonorrhoea or Chlamydia trachomatis in a sample could be detected by PCR. The procedure in brief is as follows:

1. DNA is extracted from the sample using DNA extraction buffers.

2. A master mix of pre-calculated quantities of extracted DNA, Taq polymerase and dNTP and buffers is prepared. Amplification is carried out in an automated thermal-cycler in which the sample is incubated at various temperatures sequentially in repeated cycles for 3 to 4 hours. The amplified product is visualised with a known positive control, either by Gel-Electrophoresis or ELISA using Biotinylated primers or by Immunoblotting, or by in situ hybridization. Commercialy available kits usually use an ELISA based system for detection of amplied DNA.

Appendix 5.22: Laboratory quality control procedures

Quality control procedures for laboratory tests should be developed together with the microbiologists involved in the study. A suggested scheme for such quality control procedures is:

Gram stain for NG on urethral and cervical specimens

Slides can be stored and read, blind to the original diagnoses, by a second microbiologist. This should be done relatively soon after specimen collection and slide preparation, as the quality of stored slides deteriorates substantially over time and this may lead to false negative results.

Chlamydia EIA

After sample preparation, all specimens should be refrigerated. After testing the residual, prepared specimens should be retained in a refrigerated state. All positive and an equal number of negative samples should be relabelled with fictitious code numbers. A list is kept linking the original and new code numbers. Samples are then retested, blind to the original results, within 14 days. Specimens must not be frozen.

InPouch culture

All positive and an equal number of negative samples should be relabelled with fictitious code numbers. A list is kept linking the original and new code numbers. The samples are then read the same day by a second microbiologist or lab technician who is blind to the original result.

RPR/TPHA

After centrifugation, serum should be separated into two cryovials and refrigerated. For all positive and an equal number of negative samples the second cryovial should be relabelled with a fictitious code. A list is kept linking the original and new code numbers. Samples are then tested, blind to the original result.

Urine PCR

Two aliquots of urine should be taken from each participant and stored at a temperature of - 20 degrees C or less. The temperature of the freezer should be monitored each day, both by checking the freezer thermometer and by checking that the urine samples are frozen solid inside the sample tubes. Thick ice should not be allowed to build up on the walls inside the freezer as this can act as insulation and allow a warmer temperature to develop inside the freezer.

One aliquot of urine is sent to the PCR laboratory in a frozen state. Dry ice should be obtained for this transfer. In the PCR laboratory the residuae of urine samples will be kept in the frozen state to allow retesting of samples that are equivocal for chlamydia and for processing and then retesting of samples in which the internal control assay is negative. After PCR tests have been completed, all positive (either chlamydia or gonorrhoea) and 5% of negative (both chlamydia and gonorrhoea) samples should be relabelled with fictitious code numbers. A list is kept linking the original and new code numbers. Relabelled samples are then sent in a frozen state to the PCR laboratory where they are tested, blind to the original result.

APPENDIX 5.3

CHECKLISTS OF EQUIPMENT TRAYS FOR CLINICAL INVESTIGATIONS

Checklist for E1 and E2: Preparation of trays for male STD studies

Preparation of trays for male STD study and additional urethritis study

	to provide	**consumption for one patient**
data collection forms	2	1
specimen collection forms	2	1
sticky labels	14	5 (+2 if ulcer present)
marker pen	1	-
vacutainers	2	1
needles	2	1
holder	1	-
urine containers	2	1
swabs wooden shaft	8	2 (+ 2 if ulcer present)
swabs dacron	4	1 (+ 1 if ulcer present)
slides	4	1 (+1 if ulcer present)
plastic tubes	4	1 (+1 if ulcer present)
with transport medium (transparent cap), for detection of Chlamydia		
plastic tubes	2	1 (only if ulcer present)
dry (green cap) for detection of Herpes		
small black trays for transport of slides	2	
Candle jar with candle		

The above supply is sufficient for 2 patients.

When the tray is returned after specimen collection, please check the remaining balance of swabs, tubes etc. Normally, supplies for only one patient should have been consumed.

Checklist for E3 and E4: Preparation of trays for female RTI and ANC studies

Preparation of trays for gynaecology OPD (E3) and ANC clinic (E4)

	to provide	consumption for one patient
data collection forms	2	1
specimen collection forms	2	1
sticky labels	14	5 (+ 2 if ulcer present)
marker pen	1	-
vacutainers	2	1
needles	2	1
holder	1	-
urine collection containers	2	1
swabs wooden shaft	12	4 (+ 2 if ulcer present)
swabs dacron	4	1 (+ 1 if ulcer present)
slides	8	3 (+ 1 if ulcer present)
dropper with KOH	1	-
dropper with saline	1	-
ph paper strips	2	1
InPouch culture	2	1
sterile glass tube with cotton for transport of NG swab	2	1
plastic tubes *with transport medium* (transparent cap), for detection of Chlamydia	4	1 (+1 if ulcer present)
plastic tubes *dry* (green cap) for detection of Herpes	2	1 (only if ulcer present)

The above supply is sufficient for 2 patients including one with a genital ulcer.

When the tray is returned after specimen collection, please check the remaining balance of swabs, tubes etc. Normally, supplies for only one patient should have been consumed.

APPENDIX 9.1

SUPERVISORY TASKS AND PROCEDURES

9.11 Supervision procedures for social science components of SASHI

9.12 Supervision procedures for medical components of SASHI

(N.B. Please refer to this list of procedures in conjunction with detailed descriptions of data recording, monitoring and analysis activities for the social science supervisor that are provided in Chapter 7 on Data Recording and Monitoring and in Chapter 8 on Data Analysis and Report Writing.)

9.11 Supervision procedures for social science components of SASHI

Review field diaries and activity logs regularly, if possible daily and at a minimum weekly, the frequency depending upon logistics and the requirements of the fieldworkers

- Collect, review, code and translate data collection forms weekly
- Complete code numbering on collected data collection forms and send the same for data entry/typing and filing according to the relevant stages
- Arrange data entry and storage of original Data Recording Forms
- Review data obtained on a weekly basis, ensuring completion of incomplete forms and carry out ongoing preliminary analysis to help further delineate and prioritise further data collection requirements
- Arrange access to new sites and persons where needed
- Liaise with the medical supervisor and researchers on a day-to-day basis to ensure proper coordination and planning of data collection steps which are to be carried out jointly or in chronological sequence, such as mapping of health providers, exit interviews, data from health providers
- Request informal reports from the medical team of information collected, in order to obtain leads on appropriate foci for further data collection; for example the locations from which a maximum number of STD patients report or the identification of a health provider known for treating STDs from a particular locality
- Arrange in advance with the medical supervisor the procedure and timing of the collaborative data collection steps

- Compile a weekly report on
  - data collection activities completed and those planned for the forthcoming week
  - new findings and information obtained (preliminary review and analysis of data)
  - comments on progress of activities in relation to SASHI protocol noting obstacles, successes and adjustments to protocol.

(A model Weekly Report Form and a completed example of such a form is provided below).

- Provide one copy of each Weekly Report to the SASHI Coordinator, one to the medical supervisor, and file one copy. Send copies of all weekly reports to the relevant (social science) Resource Group member(s) on a monthly basis.
- At each weekly meeting, decide on forthcoming activities through discussion and mapping (on charts) of the data collected and activities completed by the fieldworkers over the previous week. Allocate responsibility for further agreed activities within the team in collaboration with team members.
- Attend the weekly SASHI Management Team meeting to report overall progress, discuss specific obstacles or difficulties and ensure coordination with the medical component and the study overall.

Model Weekly Report Form (with a few examples of what to include).

Weekly Meeting and Weekly Report

TIME: DATE:

ATTENDEES: [give names or initials of all present]

1. Description of activities completed

   e.g. number of interviews with private practitioners

   e.g. number of indepth case histories

2. New findings and information obtained

   e.g. new information learnt from indepth case histories

   e.g. new sites identified where CSWs work

3. Difficulties experienced

   e.g. overcoming private clinic rules for interviewing
   e.g. gaining permission to interview patients

4. Next week's activity schedule

   e.g. interviews that are already planned
   e.g. planned community based discussion
   e.g. further data collection from clinics

Procedure for problems encountered during SASHI

The supervisor should respond on a day-to-day basis to problems that arise during the social component of SASHI and should actively seek out such problems during the daily (when reports are handed in) and weekly (full team) meetings with the fieldworkers. Usually local management should be sufficient, but if any serious problem which threatens the continuity or integrity of SASHI arises the supervisor should immediately inform the overall SASHI co-ordinator. Appropriate resource person(s) should be consulted for any problems if necessary, after discussion with the co-ordinator.

9.12 Supervision procedures for medical components of SASHI

Supervision of the medical components of SASHI will consist of the following activities:

- Visit the Ante-Natal Clinic (ANC) and Obstetrics and Gynaecology (Obs/Gynae) clinics where data collection is proceeding daily, to check that sampling procedures for ANC patients and vaginal discharge/putative STD cases is proceeding as per protocol; continue daily visits until sample is complete.

- Visit STD clinic site on each day there is a clinic, to review record book and check that every STD patient who meets protocol entry criteria is being recruited into the study; continue these visits until sample is complete. Record details of any STD patient not recruited for the study and review the reasons for this with the fieldworkers

- Each working day meet with each fieldworker at an agreed time to review the forms they have collected since the previous meeting. Check each questionnaire thoroughly (and review apparent errors with the fieldworker) and enter the following details of each recruited case into a log book:

  * Date
  * Fieldworker
  * Code number

* Name of patient
* Clinic from which recruited
* Details of samples which were collected
* Confirmation that questionnaire has been checked

Keep the log book in a secure place and ensure it remains confidential.

- Remove the front page (which includes the consent form) from each questionnaire and file it in a secure place. Then send the questionnaire for data entry.

- Visit the microbiology laboratory daily and review the results sheets for each test and discuss any problems that have arisen. Review the records of freezer temperature and respond to any signs that low temperatures are not being maintained.

- Each Friday obtain from the laboratory a copy of all positive test results, together with the code number of the patient. Make photocopies of these forms and send one copy to each fieldworker, one to the head of the dermatovenereology clinic, one to the head of the Obstetrics and Gynaecology clinic and file the original. Providing the laboratory results to the clinics will allow the test results to be incorporated into patient management.

- Visit the microbiology laboratory every week and review with the laboratory worker the situation regarding equipment and reagents for SASHI tests. If there is any projected shortfall then organise provision of the necessary additional supplies.

- Check the integrity of the clinical samples stored in the microbiology department on a weekly basis. Inspect the labelling of samples to ensure that labels are fixed in such a way that they remain attached to the appropriate tube and that labels are legible. Check the samples frozen at minus twenty by close visual inspection to ensure that they are being maintained in a frozen condition.

- Liase with the social supervisor and researchers on a day-to-day basis to ensure proper coordination and planning of those data collection steps which are to be carried out jointly or in chronological sequence, such as mapping of health providers, exit interviews, data from health providers.

- Attend the weekly SASHI Management Team meeting to report overall progress, discuss specific obstacles or difficulties, and ensure coordination with the social component and the study overall.

Weekly meeting and report

- Each week convene a meeting with all fieldworkers, the laboratory worker(s) and the peon. At this meeting review overall progress with the rest of the team and discuss

problems with the progress of the study. Prepare a brief (one to two page) report of each meeting, to include:

* number of STD study patients recruited in the previous week, with breakdown by sex, age and (if patients are being referred to a central facility for the purpose of the study) the original clinic they attended. Number of eligible patients who could not be recruited and the reasons for this.

* cumulative number of STD study patients recruited since study commencement, with breakdown by sex, age and the original clinic they attended. Number of eligible patients who could not be recruited and the reasons for this.

* number of ANC study patients recruited in the previous week, together with details of number of selected subjects who were not recruited and the reasons for this.

* cumulative number of ANC study patients recruited, together with details of number of selected subjects who were not recruited and the reasons for this.

Update of progress of other aspects of the study

* Male general population study
* Compilation of available data regarding STDs / RTIs in the site
* Interviews with private dermatovenereologists
* Data collection for 1 month in the private dermatovenereological clinics: progress in planning and executing this
* Progress with data entry - how many questionnaire records entered
* Problems encountered in the previous week and solutions which have been / are being attempted. Any outstanding problems on which help (non-urgent) is required.

- Give one copy of the weekly report to the overall SASHI co-ordinator, one copy to the social supervisor, and file one copy.

- Send copies of all weekly reports and weekly laboratory test reports to the relevant Resource Group members on a monthly basis.

Procedure for problems encountered during SASHI

The supervisor should respond on a day-to-day basis to problems that arise during the medical component of SASHI and should actively seek out such problems during daily meetings with the fieldworkers. Usually local management should be sufficient, but if any serious problem which threatens the continuity or integrity of SASHI arises, the supervisor should immediately inform the overall SASHI co-ordinator. Appropriate resource person(s) should be consulted for any problems, if necessary, after discussion with the co-ordinator.